Organisation for Economic Co-operation and Development

DAF/COMP/GF/WD(2025)16

Unclassified English - Or. English

7 November 2025

DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
COMPETITION COMMITTEE

Global Forum on Competition

Competition in the Healthcare Sector – Contribution from Brazil

- Session II -

1 December 2025

This contribution is submitted by Brazil under Session II of the Global Forum on Competition to be held to be held on 1-2 December 2025.

More documentation related to this discussion can be found at: oe.cd/chthc.

Mr Antonio Capobianco [Antonio.Capobianco@oecd.org]

JT03576385

Brazil

Part 1. Administrative Council for Economic Defense (CADE)

The Role of Competition Authorities in Shaping Accessible Healthcare Markets[1]

1. Introduction

1. Ensuring that healthcare markets remain accessible, high-quality, and economically sustainable requires competition authorities to look beyond traditional price metrics and engage with the institutional realities of mixed public-private systems. Brazil's recent experience shows that merger control and market studies, when paired with sectoral cooperation and data-driven methods, can mitigate risks arising from vertical integration, portfolio strategies, and the growing role of financial investors.

2. This contribution delineates how CADE has tailored its toolkit to the particularities of healthcare and pharmaceuticals, how coordination with the health regulator has enhanced the evidentiary base and the design of remedies in some cases, and why price, access, quality, and equity function as interdependent dimensions of rivalry and competition impact. It also sketches a pragmatic trajectory from reactive case handling to systematic market governance, with emphasis on early warning, structured post-merger evaluation, and transparent monitoring. The overarching objective is to safeguard competition and to ensure that users and beneficiaries can reach suitable and affordable providers and services, thereby advancing the public interest in resilient and inclusive health systems.

2. Healthcare System

2.1. CADE's Evolving Role in Healthcare Enforcement

3. Over the last decade, CADE has progressively expanded its approach to healthcare enforcement. Traditional merger control, historically focused on horizontal overlaps, has had to adapt to a sector marked by accelerated vertical integration, cross-ownership, and

[1] This paper was prepared by **Commissioner Camila Cabral Pires-Alves** and **Vitor Jardim Barbosa**, her *Head of Office*, at the **Tribunal of CADE (Brazilian Administrative Council for Economic Defense)**. It was proofread by Izabel Cristina Medina Brum and Karine Neumaan Gonçalves, in-house translators at the International Unit of CADE.

financialisation.[2] In parallel, the authority's doctrine has been shaped by large system-level transactions (Hapvida/NotreDame Intermédica[3]; Rede D'Or/SulAmérica[4]) and by technically demanding cases in essential services such as dialysis (DaVita/Brasnefro[5]). These proceedings show how consolidation reshapes not only price structures but also bargaining asymmetries, access to hospital, and diagnostic networks, including possible spillovers into the Unified Health System (SUS).

4. CADE's recent votes and studies recognise that market power in healthcare is multi-dimensional: portfolio leverage; vertical control of pivotal inputs (operated hospitals, diagnostics, and dialysis centres); and contracting power over independent providers. The Department of Economic Studies (DEE) has documented the structural drivers - concentration, verticalisation, conglomeration, and the increasing role of financial investors - alongside the emergence of large groups with cross-segment portfolios.[6] The resulting assessment challenges are well known: how to measure effective rivalry in local markets when access and referral flows matter more than list prices or when there are significant quality differences; how to evaluate vertical foreclosure risks in single-municipality settings; and how to account for dual public-private dynamics.

5. Brazil's experience shows that competition enforcement and regulatory oversight can reinforce each other when grounded in evidence and continuous institutional dialogue. CADE's recent practice in merger control and sectoral analysis demonstrates that analytical tools and data are already available and effectively used in complex markets such as healthcare and pharmaceuticals.[7] Due to the work of the Department of Economic Studies

[2] Suzuki, E.; Paris, V.; Joshi, N.; Dedet, G. *Trends in the Financialisation of Outpatient Care across OECD Countries: What do we know?* OECD Health Working Papers No. 179. Paris: OECD Publishing, 2025. Traditional merger control, historically centred on horizontal overlaps, is adapting to a sector characterised by faster vertical integration, cross ownership, and the growing role of financial investors. Recent OECD work documents the financialisation of outpatient care and the policy concerns it raises for competition and health governance across members, especially where private equity activity accelerates consolidation and reshapes incentives.

[3] **BRAZIL. Administrative Council for Economic Defense (CADE).** *Merger Case No. 08700.003390/2021-83 - Hapvida Participações e Investimentos S.A. and NotreDame Intermédica Participações S.A.*

[4] **BRAZIL. Administrative Council for Economic Defense (CADE).** *Merger Case No. 08700.004431/2022-46 - Hospital Rede D'Or São Luiz S.A. and Sul América S.A.*

[5] **BRAZIL. Administrative Council for Economic Defense (CADE).** *Concurring opinion by Commissioner Camila Cabral Pires Alves in Merger Case No. 08700.003691/2024-01 - Applicants: DaVita Brasil Participações e Serviços de Nefrologia Ltda. and Brasnefro Participações Ltda.*

[6] For detailed analysis of merger trends and market structure in Brazil's private healthcare sector, see **BRAZIL. Administrative Council for Economic Defense (CADE).** *Cadernos do Cade: Merger Cases in Health Insurance, Hospitals and Diagnostic Medicine Markets* (Revised and Updated Edition). Department of Economic Studies - DEE, Brasília, Jan. 2022, available at: https://cdn.cade.gov.br/Portal/centrais-de-conteudo/publicacoes/estudos-economicos/cadernos-do-cade/Cadernos-do-Cade_AC-saude-suplementar.pdf

[7] **BRAZIL. Administrative Council for Economic Defense (CADE).** *Cadernos do Cade: Merger Cases in Health Insurance, Hospitals and Diagnostic Medicine Markets* (Revised and Updated Edition). Department of Economic Studies – DEE, Brasília, Jan. 2022, available at: https://cdn.cade.gov.br/Portal/centrais-de-conteudo/publicacoes/estudos-economicos/cadernos-do-cade/Cadernos-do-Cade_AC-saude-suplementar.pdf

(DEE), CADE has advanced quantitative methods for measuring concentration, assessing willingness to pay, and estimating hedonic prices, which help capture multidimensional aspects of market power, including portfolio effects, vertical control, and contracting leverage.[8]

6. The next step may be strengthening coordination between enforcement and sectoral regulation, transforming early warning, case screening, and post-merger evaluation into systematic practices. CADE's recent experience in healthcare markets already reflects this evolution. The latest merger decisions have emphasised that health services, by their very nature and systemic impact, require vigilant oversight and an integrated institutional response. As stated in CADE's opinions, concentration and vertical integration in healthcare demand analytical depth, continuous monitoring, and cooperation with sectoral regulators to safeguard equitable access and effective competition.[9]

7. In cases such as *DaVita/Brasnefro*[10] and *Unimed Cascavel*[11], CADE has underlined the importance of differentiated analysis for public and private segments, the need to prevent silent consolidation processes, and the role of behavioural remedies in vertical cases combined with data reporting to enable ongoing supervision. This practice points towards a regulatory model in which competition enforcement and regulation operate as complementary instruments for detecting risks, promoting transparency, and sustaining competitive neutrality in markets of public relevance.

2.2. Cooperation with the Health Regulator: Progress and Opportunities

8. CADE and the Brazilian national regulatory agency for private health insurance (ANS) have a Technical Cooperation Agreement that enables reciprocal data sharing, joint

[8] **BRAZIL. Administrative Council for Economic Defense (CADE). Department of Economic Studies (DEE).** *Application of Willingness-to-Pay Models to the Study of Competition in the Supplementary Healthcare Sector.* Working Paper No. 03/2020. Brasília: CADE, 2020. Available at: https://www.cade.gov.br. As noted by CADE's Department of Economic Studies (DEE), the application of willingness-to-pay models allows a more accurate assessment of market power and competitive dynamics in healthcare markets, capturing how consumers value the inclusion of specific providers in health plan networks and how these relationships affect merger outcomes: "The models and procedures reviewed in this work are suitable for the analysis of the Brazilian supplementary healthcare sector and could be used, when necessary, to simulate the impact of mergers and acquisitions in both the healthcare provision and health insurance markets, providing an additional analytical tool to CADE's Commissioners and the General Superintendence. The data required for such analyses exist, even if not publicly available."

[9] **BRAZIL. Administrative Council for Economic Defense (CADE).** *Concurring opinion by Commissioner Camila Cabral Pires Alves in Merger Case No. 08700.009192/2024-10 - Unimed de Cascavel Cooperativa de Trabalho Médico and Hospital Policlínica Cascavel.* Brasília: CADE, June 30, 2025.

[10] **BRAZIL. Administrative Council for Economic Defense (CADE).** *Concurring opinion by Commissioner Camila Cabral Pires Alves in Merger Case No. 08700.003691/2024-01 - Applicants: DaVita Brasil Participações e Serviços de Nefrologia Ltda. and Brasnefro Participações Ltda.*

[11] **BRAZIL. Administrative Council for Economic Defense (CADE).** *Concurring opinion by Commissioner Camila Cabral Pires Alves in Merger Case No. 08700.009192/2024-10 - Unimed de Cascavel Cooperativa de Trabalho Médico and Hospital Policlínica Cascavel.* Brasília: CADE, June 30, 2025.

studies, and remote access to agreed databases.[12] This cooperation provides a solid institutional basis for coordinated action in healthcare markets. Brazil's experience shows that formal agreements and joint initiatives between CADE and sectoral regulators have already improved the exchange of information, the use of common data frameworks, and the mutual understanding of market dynamics. These instruments, together with the analytical capacity within both institutions, illustrate an institutional culture increasingly oriented towards integrated oversight and evidence-based policy-making**.**

9.

10. Academic research highlights that the interface between public and private healthcare spheres in Brazil operates continuously and through overlapping responsibilities, which makes cooperation a central pillar of effective governance. Building on this progress, the next phase should consolidate these mechanisms into a more structured, anticipatory framework that connects merger control, market monitoring, and regulatory planning through systematic analytical feedback. This evolution could allow cooperation to become not only reactive to specific cases, but a permanent channel for early detection of market trends and policy alignment in sectors of high social relevance.[13] [14]

11. Discussions on relevant market definition in hospital services are moving towards more granular and evidence-based segmentation. Recent merger opinions in matters such as Unimed de Cascavel with Hospital Policlínica Cascavel indicate that uniform municipal lens may fail to capture competitive realities when patient flows, referral patterns, service complexity, and insurance network design point to distinct catchment areas and service lines within the same locality. Analytical templates can enhance precision by combining quantitative elements such as travel time elasticity, patient origin and destination matrices, and service line indicators with qualitative assessments of network architecture and provider positioning.

12. There is opportunity to move from reactive collaboration to a structured programme of market intelligence. Quarterly dashboards could map concentration trends, vertical linkages, network overlaps, and referral flows using ANS administrative data combined with CADE analytics (HHI, dependency indices, travel-time-adjusted access).[15] Annual public syntheses would inform advocacy and prioritisation, while alert protocols would flag localities where merger filings or vertical moves threaten contestability before they become irreversible.[16]

[12] **BRAZIL. Administrative Council for Economic Defense (CADE); National Regulatory Agency for Private Health Insurance and Plans (ANS).** *Technical Cooperation Agreement between CADE and ANS.* Process No. 08700.005603/2018-50. SEI No. 0536234. Brasília, Dec. 10, 2018.

[13] See HADDAD, Frederico. *As interfaces público-privadas do sistema de saúde e as implicações do mercado de saúde suplementar para o SUS: conflito distributivo em movimento.* Doctoral Dissertation – University of São Paulo, Faculty of Law, 2025.

[14] A series of "*Observatórios da Concorrência*" ("Competition Observatories") meetings were held for ANS and CADE staff to present their analytical methodologies to one another and discuss issues in the supplementary healthcare sector.

[15] A component of CADE's Market Information Panel (PIM) covers the private healthcare sector (see: https://pim.cade.gov.br/).

[16] **BRAZIL. Administrative Council for Economic Defense (CADE).** *Cadernos do Cade: Merger Cases in Health Insurance, Hospitals and Diagnostic Medicine Markets* (Revised and Updated Edition). Department of Economic Studies - DEE, Brasília, Jan. 2022, available at:

13. At least two recent cases illustrate why these matter. In Unimed Cascavel/Policlínica (2025)[17], first, the Tribunal's rapporteur defined the relevant markets for general hospitals and for health insurance in the municipality of Cascavel, and then applied a structured vertical-merger test to input foreclosure and customer foreclosure, assessing capacity, incentives, and likely effects. The decision approved the transaction subject to an agreement with a package of commitments non-delisting of rival insurers, non-discrimination in contracting, maintenance of local competitive conditions, investment, governance and compliance provisions, an "open-door" policy, and a clear monitoring schedule. Each of them reflects the view that, in single-municipality settings, effective choice hinges on service breadth, quality equivalence, and timely access, and that these dimensions require continuous, data-enabled oversight.

14. In DaVita/Brasnefro (2025), CADE approached dialysis as an essential services sector in which consolidation can recalibrate bargaining and narrow effective choice unless remedies are paired with ongoing surveillance. The record highlights three concerns that inform our monitoring templates. First, **mixed financing and dual demand channels (SUS and the supplementary market)** require segmented analysis and metrics, as public provision and private clinics interact but are not interchangeable in competitive terms. Second, **serial, sub-threshold acquisitions** can accumulate into high concentration before a notifiable event occurs, which calls for forward-looking intelligence rather than case-by-case screening alone. Third**, remedies must operate as a policy instrument with embedded monitoring**: the case was cleared subject to an agreement that combined structural and behavioural measures and established data-enabled follow-up calibrated to local conditions, reflecting CADE's view that market definition is an analytical tool and that effective oversight depends on standardised and transparent indicators, and regular reporting.

15. Building on this experience, a joint CADE-ANS intelligence program should move beyond case-by-case exchanges and establish a shared observatory that aligns evidence standards, specifies a common set of indicators for screening and monitoring (for example HHI, insurer-provider dependency indices, referral flows, and travel-time-adjusted access), and publishes periodic dashboards together with a public annual synthesis, so that risk signals in municipalities and micro-regions trigger early and proportionate responses. Such programme would also standardise disclosure templates and remedies follow-ups, responding to the mixed structural and behavioural toolkit adopted in dialysis and hospital-plan cases, including divestitures, non-discrimination and access commitments, governance and compliance provisions, in addition to trustee-supported monitoring where appropriate.

2.3. Evidence Base: Current Capacities and Priorities for Institutional Uptake

16. DEE has produced a body of work that can serve as a common analytical substrate: the revised Caderno on health mergers (2022), the multi-part Essays on Supplementary Health (2023-2024), and the Working Paper on willingness-to-pay (WTP) and hedonic pricing (2020). Together, these outputs offer three building blocks: (i) a sectoral panorama with jurisprudential synthesis, including remedy typologies; (ii) empirical diagnostics and

https://cdn.cade.gov.br/Portal/centrais-de-conteudo/publicacoes/estudos-economicos/cadernos-do-cade/Cadernos-do-Cade_AC-saude-suplementar.pdf

[17] BRAZIL. Administrative Council for Economic Defense (CADE). Reporting Opinion by Commissioner Victor Oliveira Fernandes in Merger Case No. 08700.009192/2024-10 – Unimed de Cascavel – Cooperativa de Trabalho Médico and Hospital Policlínica Cascavel. Brasília: CADE, June 30, 2025

measurement cautions (e.g., the limits of using registered tariffs as price proxies); and (iii) tractable methods to value network attributes, simulate exclusion, and link network changes to plan prices and consumer surplus.[18]

17. However, these tools are still not standard inputs to enforcement and often operate in parallel to case-specific analysis. Therefore, it would be valuable to assess their use systematically, and to propose a core set of desirable tools to support consistent and forward-looking competition enforcement.

2.4. Beyond Price: Access, Quality, and Equity

18. In Brazil's mixed public-private health system, access is determined as much by inclusion in provider networks as by nominal price. Ongoing vertical integration between insurers and hospitals compresses the space for independent providers and may erode geographic coverage and patient mobility over time. CADE has begun to respond with network access commitments in individual cases, but a more anticipatory stance would align better with the dynamics of consolidation. Using ANS data on referrals and patient flows to map hospital dependencies would allow the authority to identify territories where a transaction would meaningfully reduce effective choice before irreversibility sets in.

19. Quality is a core dimension of rivalry and warrants systematic treatment, not residual consideration. In decisions such as those of Rede D'Or/SulAmérica and Unimed Cascavel, proxies including number of specialties, accreditation status, and medical-staff ratios were used to approximate service diversity. A prudent next step would be to incorporate outcome measures such as waiting times, readmission rates, and occupancy levels into screening and competitive assessment, thereby aligning merger control with broader public-health objectives.

20. This orientation accords with the OECD guidance[19] that, in essential services, competition assessment should extend beyond price. Equity is a cross-cutting concern: private coverage is concentrated in a few large groups and disproportionately located, with potential to entrench regional disparities. In this context, it is appropriate to incorporate regional competition mapping into the annual research agenda and institutionalise models to estimate how beneficiaries value network breadth, hospital quality, and plan type. A routine application of these methods would enable more precise calibration of remedies and earlier detection of harm in markets characterised by opaque prices and complex vertical relationships.

[18] Administrative Council for Economic Defense (CADE) - Department of Economic Studies (DEE). Cadernos do Cade, No. 14: Merger Cases in the Markets for Health Plans, Hospitals, and Diagnostic Medicine - Revised and Updated Edition. Brasília: CADE, 2022; CADE - Department of Economic Studies (DEE). Essays on the Supplementary Health Market (multi-part series). Brasília: CADE/DEE, 2023-2024; Lima, Tatiana de Macedo Nogueira. Application of Willingness-to-Pay Models to the Study of Competition in Supplementary Health. Working Paper No. 03/2020, Department of Economic Studies - CADE. Brasília: CADE, 2020.

[19] OECD. *Considering non-price effects in merger control* (DAF/COMP(2018)2), Background Note by the Secretariat, Paris: OECD, 2018; OECD. *Competition and regulation in the care industry*, Paris: OECD, 2024; Suzuki, E.; Paris, V.; Joshi, N.; Dedet, G. *Trends in the Financialisation of Outpatient Care across OECD Countries: What do we know?* OECD Health Working Papers No. 179, Paris: OECD Publishing, 2025, doi:10.1787/f5d88b41-en.

2.5. Market Structure and Case Experience

21. Brazil's recent cases in health care indicate a recurring triad of relevant product markets—medical-hospital services (SMH), diagnostic support services (SAD), and health plans—whose competitive dynamics are shaped by highly local patient flows on the supply side and increasingly national portfolio strategies on the demand and contracting side. In SMH, rivalry is commonly assessed at municipal or intra-municipal levels, frequently operationalised via a travel-time or catchment-area proxy (e.g., 10 km / ~20 minutes), while in SAD the product boundaries follow functional lines (clinical analyses; pathology/cytology; imaging and graphic methods, often treated as distinct markets) and geography is likewise local; for health plans, overlaps are typically mapped city by city, even when large combinations call for an assessment of broader portfolio and bargaining effects:

- Highly concentrated or system-level cases (e.g., large groups with cross-segment portfolios): In metropolitan settings where a hospital group simultaneously expands its medical-hospital services (SMH) and strengthens its diagnostics footprint (SAD) in the same locality, horizontal overlaps arise market-by-market and interact with vertical/conglomerate links (referrals, in-hospital labs, and imaging). Illustrative trajectories include Rede D'Or São Luiz's successive hospital acquisitions in Rio de Janeiro and São Paulo, alongside moves in diagnostics such as Maximagem and Laboratório Richet, and Dasa's multi-brand SAD portfolio with national capillarity (Delboni, Lavoisier, Alta, Sérgio Franco, Bronstein, Lâmina, Frischmann Aisengart, Santa Luzia, among others). In such configurations, structural or hybrid remedies—targeted local divestitures, referral firewalls/clean teams, and narrowly tailored non-acquisition or network-access safeguards—combined with robust monitoring architectures, are warranted to preserve access for independent hospitals and diagnostic networks. In these situations, policy design should promote the use of structural or hybrid remedies, complemented by monitoring frameworks to track network access, referral patterns, and patient flows, so as to preserve contestability and equitable access for independent hospitals and diagnostics.[20]
- Regional or moderately concentrated markets (e.g., Unimed Cascavel, 2024): (e.g., local health-plan rivalry with vertical links to SMH/SAD). In health plans, overlaps are predominantly municipal/local; nonetheless, large combinations may reshape bargaining with providers and incentives around network design, especially where the group is vertically integrated. The consolidation culminating in Hapvida's acquisition of control of NotreDame Intermédica reconfigured numerous local plan markets and exemplifies portfolio and vertical-integration issues that require behavioural commitments—non-discrimination, auditable network-access criteria, and periodic reporting—paired with continuous inter-agency oversight. Likewise, the experience with Unimed-system transactions in medium-sized cities shows competition risks where a leading local plan is closely tied to provider assets. In previous matters involving Unimed entities and local hospitals, CADE took a strict view when overlaps would result in very high shares and limited entry prospects. Rivalry remains feasible, but vertical integration may limit network access. Behavioural commitments - non-discrimination, auditable network-access criteria, and TISS-based reporting - are

[20] Caderno DEE: Mergers in Health Markets (2022) - sectoral diagnosis and consolidation trends; monitoring and remedy patterns.

appropriate if paired with continuous oversight and inter-agency monitoring capacity.[21] [22]

- Fragmented/asymmetric markets with national consolidation (e.g., DaVita/Brasnefro): Fragmented/asymmetric markets with national consolidation (e.g., dialysis within SAD).
  In dialysis and other procedure-based SAD segments, assessing portfolio effects across cities and contracts—and distinguishing public (SUS) from private network interfaces—is central. Recent deliberations in transactions involving DaVita brought to the fore the national concentration of dialysis services, the role of SUS financing, and concerns that serial below-threshold acquisitions may erode the viability of independent clinics. Therefore, monitoring templates should separate SUS and private effects (chair occupancy, cancellations, distance to facility, referral acceptance, and adverse-event reporting) and tie disclosure to clear escalation triggers under a joint CADE–Anvisa–ANS protocol. Measurement of portfolio x effects across services and public-private interfaces is key; monitoring templates must distinguish SUS and private-network effects.[23] [24]

22. Beyond individual case typologies, the Tribunal's recent decisions point to five transversal lessons. First, essential health care markets merit priority and sustained vigilance regarding vertical integration and portfolio strategies across the care chain, given the attendant risks of foreclosure, discriminatory access, and bargaining asymmetries for independent providers. Second, parameters adopted in earlier cases should be revisited and, where appropriate, recalibrated to reflect new structural realities, with finer segmentation by product line and explicit attention to interactions with the Unified Health System. Third, coordination across public bodies needs to be strengthened in order to remove regulatory frictions and enhance the design, implementation, and monitoring of remedies. Fourth, closer scrutiny is warranted for sequential or non-transparent transactions that may cumulatively alter market structure or circumvent previous decisions. Fifth, healthcare merger reviews should move beyond price metrics to systematically include quality, access, and equity indicators.

23. In summary, merger control in health care has matured; however, a fully systematised methodology for vertical, conglomerate, and dynamic effects remains to be

[21] **BRAZIL. Administrative Council for Economic Defense (CADE).** *Concurring opinion by Commissioner Camila Cabral Pires Alves in Merger Case No. 08700.009192/2024-10 - Unimed de Cascavel Cooperativa de Trabalho Médico and Hospital Policlínica Cascavel.* Brasília: CADE, June 30, 2025.

[22]Since TISS data capture actual healthcare services provided, additional confidentiality safeguards usually apply when these datasets are shared or used for analysis. Even with anonymized beneficiaries, granular variables such as identifiers of institutions or detailed geographic information (ZIP code or neighborhood) are often aggregated or generalized, which may limit the analytical potential of the data.

[23] **BRAZIL. Administrative Council for Economic Defense (CADE).** *Concurring opinion by Commissioner Camila Cabral Pires Alves in Merger Case No. 08700.003691/2024-01 - Applicants: DaVita Brasil Participações e Serviços de Nefrologia Ltda. and Brasnefro Participações Ltda.*

[24] See HADDAD, Frederico. *As interfaces público-privadas do sistema de saúde e as implicações do mercado de saúde suplementar para o SUS: conflito distributivo em movimento.* Doctoral Dissertation - University of São Paulo, Faculty of Law, 2025.

consolidated. Institutional uptake could be advanced by embedding existing analytical tools into routine screenings and post-merger evaluations, adopting harmonised metrics and disclosure templates, and consolidating CADE-ANS cooperation into a standing market-intelligence function oriented to anticipatory enforcement and iterative learning - on the premise that durable progress rests on shared evidence, repeatable processes, and sustained inter-agency coordination.

3. Pharmaceutical Sector

3.1. Competition Risks Across the Pharmaceutical Value Chain

24. Pharmaceutical markets exhibit a distinct but complementary risk profile relative to healthcare provision. Portfolio leverage in distribution and among multinational manufacturers, strategies that extend exclusivity in patented drugs, and vertical control over hospital procurement and emerging digital channels recur in consultations and complaints, yet they often stop short of formal proceedings because information is fragmented and the evidentiary burden is high in a tightly regulated environment. A coordinated analytical effort on drug distribution and procurement — drawing on the insights of the 2025 CADE Working Paper: Pharmaceutical Manufacturing for Human Use — could provide a useful basis for consolidating existing knowledge and identifying areas that warrant further examination. Rather than defining a fixed framework in advance, such an initiative would facilitate a progressive process of evidence generation and exchange, promoting constructive engagement among enforcement authorities, regulators, and market participants. Over time, this approach contributes to the establishment of shared factual baselines and a more coherent understanding of competitive risks, supporting consistency in enforcement and reinforcing the analytical foundations of policy advocacy.

25. Effective oversight turns on regulatory alignment. Cooperation among CADE, the Brazilian Health Regulatory Agency (ANVISA), and the Brazilian National Institute of Industrial Property (INPI) has generated useful exchanges, but the absence of a shared analytical framework limits policy traction. A structured inter-agency workplan could embed competition considerations upstream in price regulation, generic entry, and procurement design, reducing reliance on ex post conduct cases. Such framework would specify data access protocols, standard indicators for screening and monitoring, and clear pathways for iterative feedback among case work, market studies, and regulatory planning.

26. Digitalisation introduces an additional set of risks that require careful and informed oversight.[25] Algorithmic pricing and digital intermediation in diagnostics and pharmaceutical distribution raise legitimate questions regarding transparency, auditability, and potential discriminatory effects. The analytical expertise developed through CADE's work in digital markets can be adapted to these contexts, including through the refinement of algorithmic screening tools, the gradual adoption of disclosure standards on pricing logic and data sources, and the coordinated inquiries with data-protection and sectoral authorities.

Such measures would not aim to replicate digital regulation, but rather to ensure that competition assessment remains capable of identifying distortions and reinforcing accountability where technological opacity may conceal anticompetitive conducts. Over

[25] The emergence of new types of medicines, such as gene therapies, calls for the development of innovative payment models. These may include risk-sharing arrangements among pharmaceutical companies, government bodies, insurers, and healthcare providers, designed to ensure patient access while maintaining financial sustainability.

time, this approach could contribute to a governance framework in which competition policy, regulatory design, and data stewardship evolve in parallel - each informing the other, without overreach, and maintaining a balance between innovation and public trust.

27. Under Article 19 of Law No. 12529/2011, the Secretariat for Economic Monitoring (SEAE) is mandated to promote competition across government, including through regulatory reviews, impact assessments, and sectoral studies. Within the health and pharmaceutical domains, SEAE is currently exercising this mandate under the ongoing Regulatory and Competition Assessment Procedure (PARC), in collaboration with Anvisa, through a comprehensive evaluation of the rules and parameters established by the Brazilian Drug Market Regulation Chamber (CMED) — the inter-ministerial body responsible for medicine price regulation. CMED, for which Anvisa serves as executive secretariat, sets ceiling prices at the factory level (PF), at retail (PMC), and for government procurement (PMVG), and periodically updates these parameters by resolution. The criteria for pricing new medicines and presentations are established in CMED Resolution 2/2004, which defines categories and international reference pricing rules. Strengthening analytical and procedural links among these functions — enforcement, price regulation, and policy advocacy — would enable a more integrated approach to competition and access, consistent with the broader objective of resilient and equitable health systems.

4. Conclusion

28. Brazil's experience reflects a substantial progress and a growing capacity to address complex interactions between competition policy and health regulation. CADE's analytical and institutional foundations are sound. The focus is on strengthening knowledge generation, enhancing policy coherence, and promoting operational complementarity across institutions. The progress in empirical analysis and merger control can serve as a foundation for a more integrated oversight, where evidence gathered through casework, market studies, and regulatory monitoring informs policy in both preventive and corrective measures. A constructive way forward is to conduct periodic market studies in healthcare and pharmaceuticals that create a shared empirical reference for screening, remedy design, and post-merger evaluation.

29. At the same time, the cooperation with the Brazilian national regulatory agency for private health insurance (ANS) and the Brazilian Health Regulatory Agency (ANVISA) can evolve into a more structured partnership, where findings from competition cases inform regulatory planning and regulatory frameworks guide the assessment of competitive effects. Embedding economic evidence in regulatory impact assessments and strengthening the capacity to monitor remedies over time would foster consistent and transparent supervision across sectors.

30. Brazil's experience demonstrates steady and sustained progress in developing the analytical and institutional capacities needed to manage competition in the health sector. The current focus is on consolidating these achievements through stronger knowledge generation, greater policy coherence, and closer operational coordination among institutions. Conducting periodic market studies in healthcare and pharmaceuticals can serve as a shared empirical foundation for screening, remedy design, and evaluation, while cooperating with ANS and ANVISA can enhance consistency between competition assessments and regulatory frameworks. Embedding economic evidence in regulatory planning and reinforcing monitoring capacities would promote more transparent, predictable, and effective oversight. Taken together, these efforts demonstrate a commitment to governance that values evidence, coordination, and gradual institutional learning.

Part 2. Brazil's Secretariat for Economic Reforms (SRE)

1. This contribution provides an overview of the main regulatory and competition advocacy initiatives undertaken by the Secretariat for Economic Reforms (SRE) of the Ministry of Finance in the Brazilian pharmaceutical market. In addition to a review of the regulatory framework (Section 2), it presents an analysis of market evolution and the key challenges faced by regulators (Section 3). The report also details SRE's efforts to promote competition as a member of the Drug Market Regulation Chamber (CMED), the interministerial body responsible for defining the pharmaceutical pricing regulatory framework (Section 4), and highlights two ongoing market studies (Section 5).

1. Introduction

2. Brazil's healthcare expenditures represent 9.6% of GDP, a share higher than in most other Latin American countries. Moreover, out-of-pocket payments account for approximately 25% of total health expenditures — significantly above the OECD average of 20%. This structure underscores the substantial financial burden on households, particularly in the context of rising healthcare demand and increasing treatment costs driven by technological innovation and population ageing.

3. A large proportion of these out-of-pocket expenditures is allocated to the purchase of medicines, given that private health insurance coverage in Brazil is mostly restricted to hospital-based pharmaceuticals. As a result, ensuring that medicine prices remain affordable has become a critical regulatory priority to uphold the constitutional principles of universality and equity in healthcare. The interplay between affordability, regulation, and market competition is therefore central to ensuring sustainable access to essential treatments and narrowing healthcare outcome gaps across income groups.

4. The economic regulation of pharmaceutical markets is one of the most sensitive areas of public health policy, balancing the need to stimulate innovation with the obligation to guarantee affordability and fair access. In recent years, however, Brazil's pricing framework has faced new challenges. The emergence of high-cost therapies, the rapid pace of technological innovation, and the reliance on an inflation-based adjustment mechanism—combined with the absence of provisions for downward price revisions—have exposed the structural limitations of Brazil's current regulatory and pricing framework. These developments highlight the urgency of regulatory modernization to enhance transparency, efficiency, and alignment between pricing policies and public health objectives.

5. Against this backdrop, the present report outlines the competition advocacy initiatives led by the Secretariat for Economic Reforms (SRE)[26] of the Ministry of Finance, which, aside from having a competition advocacy mandate, holds a particularly strategic position to influence pharmaceutical regulation, since it has a permanent seat on the interministerial body responsible for defining the regulatory framework of the

[26] Within the Brazilian System for Economic Defense (SBDC), the SRE, specifically through its Secretariat for Economic Monitoring (SEAE), executes a consolidated advisory role in competition advocacy, in accordance to Law No. 12,529/2011. It issues opinions on normative acts and legislative proposals that may impact competition, as well as preparing sectoral studies to assess situations in various sectors of the economy, proposing a review of laws and regulations that may be seen as anticompetitive.

pharmaceutical market, the Drug Market Regulation Chamber (CMED).[27] Section 2 outlines the Brazilian Pharmaceutical Regulatory Framework, including its institutional structure and mechanisms for pricing regulation. Section 3 presents an overview of the Brazilian pharmaceutical market. Sections 4 and 5 analyze SRE's competition advocacy initiatives: Section 4 focuses on regulatory engagement within CMED, while Section 5 examines initiatives under the Regulatory and Competition Assessment Procedure (PARC) framework, conducted by SRE.

2. The Brazilian Pharmaceutical Regulatory Framework: Institutional Design and Price Regulation

6. Brazil's pharmaceutical regulatory framework is characterized by an interdependent institutional structure that integrates health, industrial, and economic dimensions. Several agencies are involved throughout the medicine life cycle, including the Brazilian Health Regulatory Agency (Anvisa), responsible for health and safety regulation; the Drug Market Regulation Chamber (CMED), which oversees economic regulation; and the National Committee for Health Technology Incorporation (Conitec), which conducts health technology assessments and makes reimbursement decisions for the public health system (SUS). Together, these bodies govern the processes of market entry, pricing, and incorporation into the public health system, ensuring that medicines meet both public health and economic objectives.

7. Anvisa is the cornerstone of health and safety oversight, responsible for the authorization of clinical trials, marketing approvals, inspections, and post-market surveillance of drugs. Marketing authorizations are generally valid for ten years, with specific renewal conditions for medicines targeting rare diseases or emergency public health needs. Within the Unified Health System (SUS), medicine access follows a value-based approach led by Conitec, which conducts evidence-based appraisals prior to incorporation. These evaluations rely on Health Technology Assessment (HTA) methodologies that combine clinical efficacy, safety, and economic evaluations such as cost-effectiveness and budget impact.

8.

9. Parallel to Anvisa's health mandate, CMED oversees the economic regulation of the pharmaceutical market, with authority to define maximum wholesale and retail prices, and minimum mandatory discounts for public procurement. CMED's main regulatory instrument, Resolution No. 02/2004, currently under revision, establishes the methodology for setting price ceilings according to innovation level and therapeutic gain.

10. CMED sets maximum prices using two main methodologies: **external reference pricing (ERP)**, which benchmarks domestic prices against those in a basket of reference countries[28] and the product's country of origin; and **internal reference pricing (IRP)**, which compares proposed prices with those of identical or therapeutically equivalent medicines already available in the Brazilian market. In all cases, the final approved price corresponds to the lowest value among the ERP and/or IRP benchmarks and the price proposed by the applicant. Manufacturers must apply for price approval before

[27] CMED is composed of representatives from the Ministry of Health, the Civil Cabinet of the Presidency (Casa Civil), the Ministry of Justice and Public Security, the Ministry of Finance, the Ministry of Development, Industry, Trade and Services, and the Brazilian Health Regulatory Agency (Anvisa).

[28] Australia, Canada, Spain, the United States, France, Greece, Italy, New Zealand, and Portugal

commercialization, and violations such as exceeding the authorized ceiling are subject to sanctions. Generic medicines are priced at 65% of the reference product. To foster price competition and enhance transparency in prescribing practices, medical prescriptions are required to be issued based on the active substance rather than the brand name.

11. The price cap system is composed of three main thresholds: the **ex-factory price (PF)**, which represents the maximum price at which manufacturers or distributors may sell medicines in the Brazilian market; the **maximum consumer price (PMC)**, which defines the upper limit charged by pharmacies and drugstores to end users; In addition, Resolution No. 3/2011 sets a minimum compulsory discount for government acquisitions. It obligates sellers to apply a reduction, referred to as the Price Adequacy Coefficient (CAP), of around 20% off the wholesale price for specific drugs deemed essential to public health programs. The maximum government procurement price (PMVG) applies to purchases by federal, state, and municipal authorities and includes drugs supplied through specialized pharmaceutical programs, oncology treatments, and those provided in compliance with judicial rulings.

12. Prices ceilings are updated annually based on inflation, productivity (Factor X), inter-sector price alignment (Factor Y), and intra-sector competitiveness (Factor Z), with lower adjustments permitted for more concentrated markets.

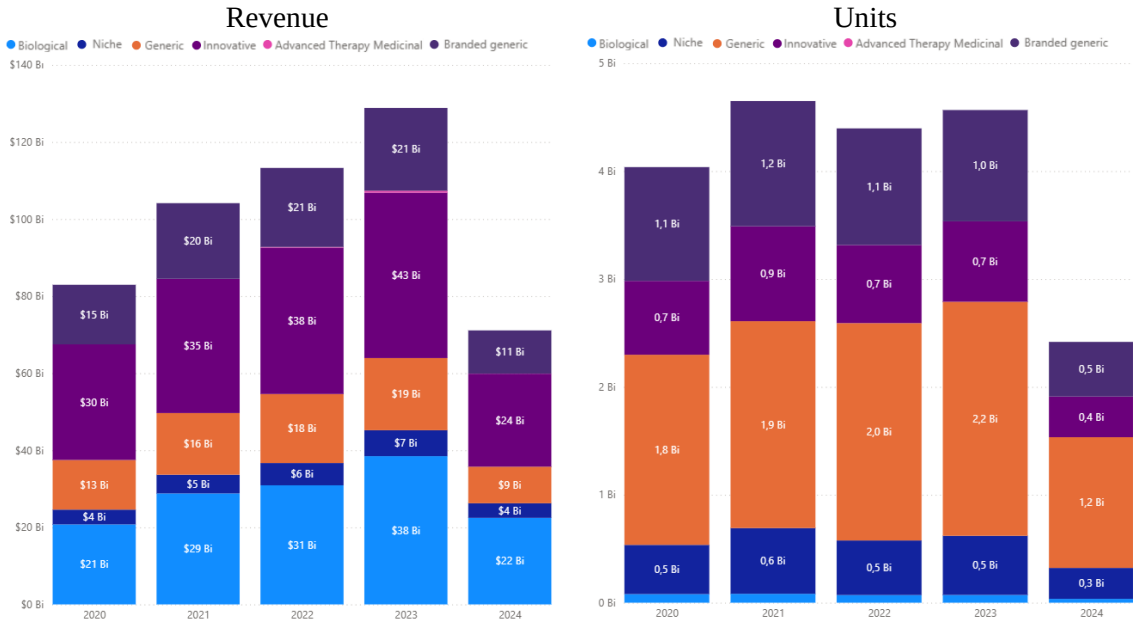
13. While the model provides predictability and stability, it has also shown limited flexibility in responding to market evolution. Brazil's system does not include mechanisms for downward adjustments, meaning that prices may remain indexed to inflation even when international reference prices or production costs decline. This rigidity, coupled with variation in initial price-setting, has contributed to persistent discrepancies between regulated ceiling prices and actual transaction values, weakening the regulator's capacity to promote affordability and competitive parity across therapeutic categories. In addition, differences in approval timelines and exchange rate fluctuations can result in price misalignments for equivalent medicines, which in some cases reduce competitive pressures among market participants.

14. Addressing these limitations requires incorporating competition analysis into the price regulation framework. Through its participation in CMED, the Ministry of Finance has engaged in more direct competition advocacy as part of broader regulatory modernization initiatives, as will be discussed in section 4.

3. The Panorama of the Brazilian Pharmaceutical Market

15. As in many other countries, Brazil is experiencing rising pharmaceutical expenditures, driven by longer life expectancy, rapid technological innovation, and the increasing cost of new therapies. Between 2020 and 2023, industry revenues grew from BRL 83 billion (EUR 13.3 billion) to BRL 128 billion (EUR 20.5 billion) – a 55% increase – while the number of units sold rose by only 13%. This indicates that expenditure growth has been primarily price-driven, rather than the result of higher consumption.

Figure 1. Evolution of Revenue and Units Sold from 2020 to the First Half of 2024, by Product Type



Source: SAMMED Data, CMED. Author's elaboration. Revenues are expressed in Brazilian reais (BRL).

16. A closer examination of the data reveals that expenditure growth is highly concentrated in innovative and biological medicines, whose revenues are comparable to the combined sales of generics and similar drugs, despite accounting for a much smaller share of total units sold.

17. The rise of high-cost drugs and advanced therapies targeting rare or complex diseases has further amplified this trend, as these treatments rely on sophisticated technologies and are launched at substantially higher prices. In Brazil, between 2020 and 2024, the number of medicine presentations with a price ceiling above BRL 10,000 (EUR 1,600) more than doubled, rising from 240 to around 600, with nine exceeding BRL 500,000 (EUR 80,000). Revenue from these products also increased sharply, from BRL 7.5 billion (EUR 1.2 billion) in 2020 to BRL 22.6 billion (EUR 3.7 billion) in 2023.

18. Besides that, an analysis conducted by the Secretariat for Economic Reforms (SRE) comparing average transaction prices with official factory price ceilings revealed significant misalignments between regulated and market prices. Between 2021 and 2023, over half of all drugs were sold at discounts exceeding 50% relative to CMED's ceiling prices, a pattern primarily driven by generic medicines.[29]

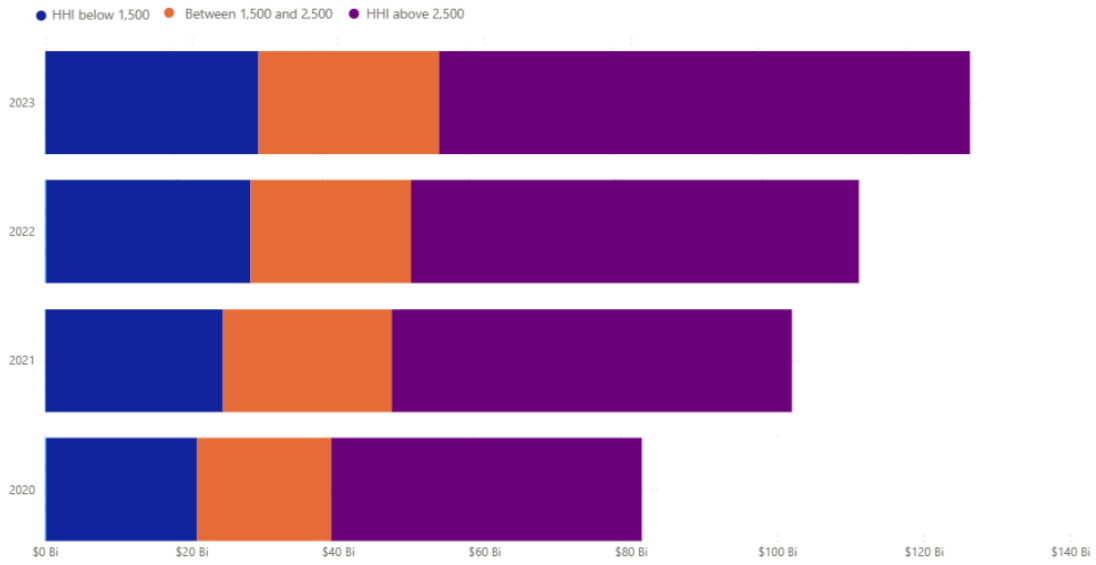
19. In contrast, high-priced drugs generally face limited or no competition from generics or therapeutic substitutes, which reduces competitive pressure and keeps prices

[29] Besides that, the prevalence of large discounts may be interpreted as evidence of more competitive markets, where rivalry drives commercial prices far below the regulated ceiling. However, such discrepancies also highlight potential limitations of the regulatory framework. In markets where vulnerable buyers rely on the regulated ceiling to ensure affordability, a ceiling disconnected from market realities may reduce the regulator's capacity to protect smaller purchasers, particularly in hospital procurement. Conversely, in markets characterized by lower discounts, the apparent alignment with the ceiling may not necessarily indicate regulatory effectiveness. Instead, it could reflect weaker competition, greater pricing power for manufacturers, and risks of higher expenditure and reduced patient access.

close to the regulated ceiling. For example, 65% of medicines with a price cap above BRL 10,000 (EUR 1,600) are sold with discounts of less than 20%. This pattern illustrates significant variation in discount practices across product types and reflects differences in competitive intensity within market segments, underscoring the challenges of fostering price competition and ensuring affordable access to high-cost therapies.

20. Regarding market concentration, both the Administrative Council for Economic Defense (CADE) and the Drug Market Regulation Chamber (CMED) typically apply the Anatomical Therapeutic Chemical (ATC) classification system – specifically level 4, corresponding to the therapeutic subgroup – as the reference framework for defining relevant markets. In Brazil, there are 1,905 active ingredients distributed across 509 therapeutic subclasses, underscoring the sector's diversity and complexity. Herfindahl-Hirschman Index (HHI) estimates (figure 2) indicate that approximately 55% of pharmaceutical revenues are generated in markets with HHI values above 2,500, a level that denotes high concentration and limited competitive intensity in a significant share of the industry.

Figure 2. Pharmaceutical Sector Revenue by Therapeutic Class HHI Range, 2020–2023

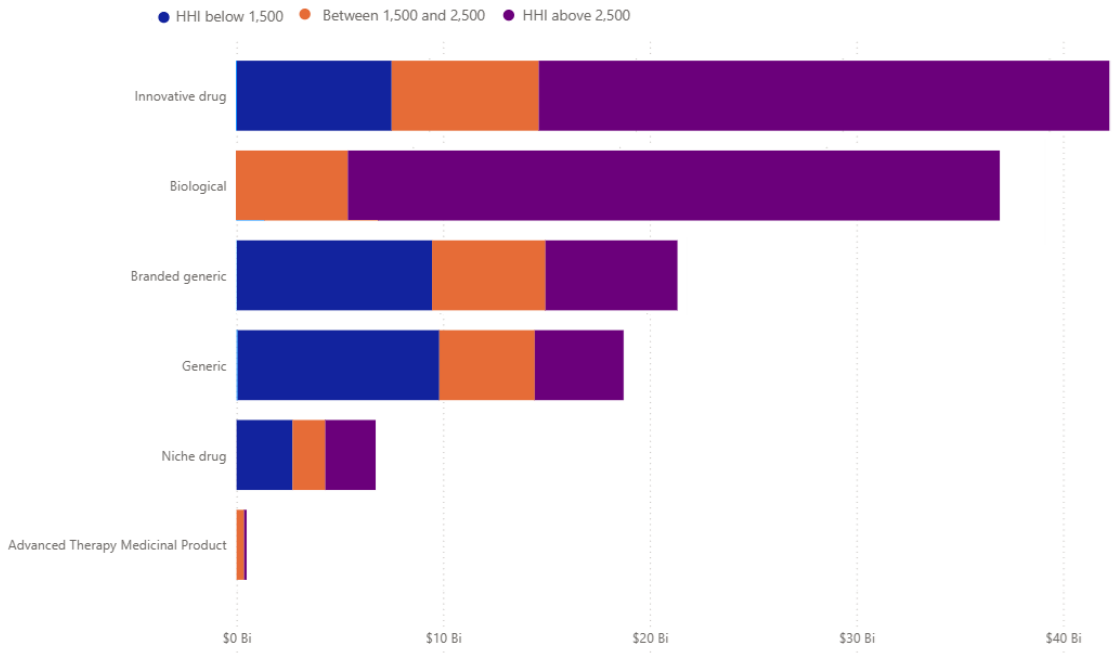


Source: SAMMED Data, CMED. Author's elaboration. Revenues are expressed in Brazilian reais (BRL).

21. Innovative medicines and biologicals exhibit the highest concentration levels (figure 3), with a substantial share of revenues derived from markets with HHI values exceeding 2,500. Such findings point to limited competitive pressures and a structural predisposition toward oligopolistic or monopolistic market configurations, highlighting the need for continued monitoring and competition-sensitive regulatory design in these segments.

22. Niche drugs and advanced therapy medicinal products (ATMPs), although accounting for smaller overall market shares, also reveal a concentration profile tilted toward higher HHI levels, consistent with their specialized scope and barriers to competition.

Figure 3. Pharmaceutical Sector Revenue by Therapeutic Class HHI Range and Medicine Type in 2023



Source: SAMMED Data, CMED. Author's elaboration. Revenues are expressed in Brazilian reais (BRL).

23. By contrast, the markets for branded generics and generics are comparatively less concentrated, displaying a broader distribution across the moderate (1,500–2,500) and low (<1,500) HHI ranges, which signals the presence of more competition.

24. Taken together, this panorama highlights a dual structure of the pharmaceutical sector: on one side, highly concentrated markets for innovative and complex products, where competition is structurally limited; on the other, relatively more competitive environments in the generic segments, which contribute to price discipline and broader accessibility. This suggests that economic regulation through CMED is not merely a formality but a critical tool to mitigate monopolistic pricing power, especially given that concentrated markets accounted for more than 55% of sector revenues in 2023.

25. From a legal and regulatory perspective, these trends raise critical questions about the influence of regulatory frameworks on market dynamics and the extent to which institutional arrangements can mitigate or exacerbate inequalities in access to medicines. It is under these circumstances that the Secretariat for Economic Reforms (SRE) has structured its competition advocacy initiatives, which will be discussed in detail in the following section.

4. Competition Advocacy through Regulatory Engagement in CMED

26. In Brazil, the Ministry of Finance (MF), through the Secretariat for Economic Reforms (SRE), has a mandate established in the Brazilian Competition Law to promote competition across government public policies. SRE also plays a formal and strategic role

in the governance of pharmaceutical pricing through its participation in the Drug Market Regulation Chamber (CMED).

27. As a permanent member of CMED's interministerial board, alongside the Ministries of Health, Justice, Industry and Trade and the Civil Cabinet of the Presidency, the SRE within the MF contributes directly to the formulation, revision, and oversight of pricing regulations. Given CMED's consensus-based decision-making structure, the Ministry's engagement in this forum carries an inherent advocacy dimension, enabling it to systematically promote competition-oriented perspectives within the regulatory decision-making process.

4.1. Regulatory and Institutional Reforms in Brazil's Pharmaceutical Price Regulation Framework

28. Recognizing that the framework established by Resolution CMED No. 2/2004 no longer reflected current market dynamics or technological developments, CMED, with the active participation of the Ministry of Finance, initiated a comprehensive revision process.

29. The reform was preceded by public consultation and supported by a regulatory impact assessment to ensure evidence-based decision-making. The revised resolution, which is now in its final drafting stage, seeks to enhance transparency, predictability, and procedural fairness in price regulation. It aims to modernize pricing methodologies for new medicines and presentations and introduce clearer procedures for the pricing of medicines classified as biosimilars. This process represents the first major update to Brazil's economic regulation of medicines in two decades. Besides that, technical discussions are underway on developing a pricing methodology for advanced therapies and medicines with incremental innovation, in line with guidelines aimed at improving quality and enhancing regulatory legal certainty, while also fostering greater access to medicines incorporating new technologies

30. In parallel, additional regulatory initiatives are being developed under CMED's coordination to address evolving challenges in the pharmaceutical sector. These include consultations on specific pricing methodologies for Advanced Therapy Medicinal Products (ATMPs) and updates to CMED's internal governance rules to streamline decision-making, and expand opportunities for dialogue between regulators and stakeholders. These procedural improvements aim to increase regulatory legitimacy, consistency, and efficiency.

31. CMED is also reviewing its Resolution on Sanctioning Procedures, which establishes the administrative process for investigating and penalizing violations of pricing and transparency rules. The revision seeks to enhance the effectiveness and proportionality of sanctions, ensure faster case resolution, and strengthen deterrence against non-compliance. By improving enforcement mechanisms, the reform aims to increase market discipline and ensure that regulatory and competitive conditions are applied uniformly across all market participants.

32. For the next initiatives, one of the key areas identified for regulatory improvement concerns Brazil's current price adjustment model, which operates without periodic realignments to reflect actual market conditions. This rigidity has led to a growing divergence between regulated ceiling prices and effective transaction values, thereby constraining the regulator's capacity to influence competitive dynamics, promote price efficiency, and safeguard consumer welfare. Discussions are ongoing regarding the introduction of positive and negative extraordinary price adjustments, after Provisional

Measure No. 754/2016, which expressly allowed CMED to review and reduce prices, failed to be converted into law.

33. Taken together, these reforms are expected to foster a more competitive pharmaceutical environment in Brazil. By clarifying the pricing framework and reducing administrative uncertainty, the new regulation will lower entry barriers for generics, biosimilars, and innovative products. Greater transparency and consistency in regulatory procedures are also expected to discourage strategic litigation and regulatory delays, promoting fairer competition and more predictable market conditions. Ultimately, these initiatives reinforce the alignment between public health objectives and competition principles, supporting innovation, affordability, and access to medicines in Brazil.

5. Competition Advocacy through PARC

34. In addition to its competition advocacy activities through regulatory engagement in CMED, the Ministry of Finance also conducts more traditional forms of competition advocacy within the pharmaceutical sector, notably through market studies assessing the competitive effects of regulation.

35. The following subsections present two evidence-based market studies, one related to the marketing authorization process conducted by Anvisa, while the other concerns the definition of medicine's entry prices in the market. Both were developed under the Regulatory and Competition Assessment Procedure (PARC)[30]-[31] framework, a SRE's initiative which aims to identify regulation that may lead to anticompetitive outcomes and to propose pro-competitive regulatory reforms that enhance market efficiency.

5.1. Regulation on the Marketing Authorization of Medicines

36. In Brazil, the marketing authorization of medicines is governed by a set of resolutions and normative instructions issued by Anvisa, which establish the quality, safety, and efficacy requirements to be demonstrated through technical and clinical dossiers submitted to the regulator. These processes are costly and time-consuming and can at times constitute a regulatory barrier to market entry. To address this, and as provided under Article 41[32] of Law No. 9,782/1999, Anvisa has implemented a range of prioritization and

[30] The Regulatory and Competition Assessment Procedure (PARC), established under Regulation SRE No. 12/2024, provides a structured mechanism for market participants and stakeholders to identify and submit potentially anticompetitive regulations for review. The process is initiated through public consultations, which invite contributions and suggestions regarding regulatory provisions that may distort competition or create unnecessary barriers to entry. Following each consultation, the Secretariat for Economic Reforms (SRE) issues a formal decision identifying the regulations selected for detailed assessment. This selection is based on a technical evaluation that considers factors such as public interest, the potential competitive impact of the regulation, and whether a competition assessment was conducted prior to its adoption, among other criteria.

[31] Brazil, through the PARC initiative, won the 2025 Competition Advocacy Contest organized by the ICN and the World Bank, in Theme 4 – *Raising Awareness of Competition by Communicating on Impact and Results.*

[32] Law No. 9,782/1999 provides, in Article 41, for the possibility of simplifying registration procedures to reduce bureaucracy and expedite regulatory processes, provided that such simplification does not compromise public health or the government's ability to oversee production and distribution activities.

simplification measures for the registration, post-registration, and renewal of medicines, including the simplified procedure linked to an existing approved dossier.

37. In place since 2014, this simplified procedure was originally designed to streamline medicine registration regulatory processes by eliminating duplications in the review of dossiers containing technical and clinical reports of equivalent medicines, thereby expediting registration and facilitating the timely entry of alternative products into the market. Besides that, eliminating redundant evaluations and ensuring consistency in decision-making, the simplified pathway enhances regulatory efficiency and facilitates the faster entry of alternative medicines into the market, ultimately supporting competition and access objectives.

38. In the first 2025 cycle of PARC, one of the topics selected for analysis was Anvisa's Resolution No. 954/2024, which introduced new restrictions on the simplified registration procedure for medicines. The resolution limits the simplified route to holders of the original (matrix) registration and companies within the same economic group. Other firms must undergo the standard registration process, which involves substantially higher administrative burdens and longer approval times: up to three years compared to two to six months under the simplified pathway. Thereby increasing entry costs and deterring potential competitors.

39. The next step in the PARC procedure is for the SRE to determine whether such restrictions could reduce the supply capacity of medicines and may artificially reinforce incumbents' competitive advantages, leading to higher market concentration and possible price escalation. These outcomes could, in turn, limit consumer access to medicines by reducing both availability and affordability. To inform this assessment, the SRE held several meetings with Anvisa to discuss its formal representation on the regulation, providing input on potential competition concerns and market impacts.

40. Should the SRE identify competition-related issues, it will hold further discussions with Anvisa to explore whether the agency's legitimate objectives of ensuring product safety, quality, and efficacy could be achieved through regulatory adjustments that also preserve competitive conditions.

5.2. Price Regulation Framework for Newly Approved Medicines

41. Another topic for analysis selected within the framework of the Regulatory and Competition Assessment Procedure (PARC) focused on assessing the competitive implications of Resolution CMED No. 2/2004, which establishes the criteria for defining medicine price ceilings in Brazil.

42. The analysis was based on contributions submitted during the first 2025 PARC public consultation, which highlighted that the current framework may distort competition and weaken price discipline across the pharmaceutical sector. A key issue identified is the coexistence of distinct price ceilings for branded identical medicines – those with the same active ingredient, dosage form, and strength – arising solely from differences in market entry dates or the identity of the manufacturer holding the marketing authorization. As a result, it is common in Brazil to find equivalent medicines from different laboratories with price ceilings at levels that vary by more than 40%, despite being therapeutically interchangeable.

43. In this context, according to the Brazilian Competition Authority's Department of Economic Studies (DEE/CADE, Technical Note No. 16/2022), unequal pricing across manufacturers would grant artificial competitive advantages to certain firms. Such discrepancies amplify pricing power for firms with higher ceilings, especially in hospital and private insurance markets, where reimbursement practices are often tied to CMED's maximum prices. Consequently, providers are incentivized to prioritize higher-ceiling products for economic reasons rather than therapeutic superiority or higher discounts, thereby distorting market competition and inflating system-wide healthcare costs.

44. Another competition concern raised by stakeholders relates to the linkage of generic prices to a fixed percentage of the originator's price ceiling, which may inadvertently create barriers to entry for generic medicines. When the company holding the reference product's registration requests a reduction in its maximum authorized price, new generics entering the market become subject to even lower price caps. In such cases, stakeholders argue that pricing policy, rather than fostering competition, may unintentionally create entry barriers and limit the diversity of therapeutic alternatives available to consumers.

45. The SRE is conducting its analysis based on data collected from regulatory authorities, pharmaceutical companies, hospitals, health insurance operators, and industry associations. The topic has also been discussed within CMED meetings, reflecting its relevance to the broader regulatory agenda.

46. Resolution No. 2/2004 remains a cornerstone of Brazil's pharmaceutical price control framework. Given its central role, the next step for the SRE is to assess whether the regulation may generate anticompetitive effects and, if so, to identify mechanisms to mitigate these risks while maintaining its effectiveness in ensuring price discipline.

6. Conclusion

47. In conclusion, Brazil's pharmaceutical market faces significant challenges in balancing affordability, access, and innovation. High out-of-pocket expenditures, combined with the growing prevalence of high-cost therapies and rapid technological advancements, underscore the critical need for regulatory frameworks that promote both efficiency and equity. The analysis presented in this report highlights structural limitations in the current pricing system, including the reliance on inflation-based adjustments and the absence of mechanisms for downward price revisions, which may constrain competition and limit access to essential medicines.

48. The Secretariat for Economic Reforms (SRE) plays a pivotal role in addressing these challenges by leveraging its position within CMED to advance competition-sensitive regulatory reforms. Through targeted advocacy and engagement with regulatory authorities, the SRE seeks to identify and mitigate potential anticompetitive effects of existing rules, while contributing to the development of pricing methodologies that support affordability without compromising innovation or product quality. These initiatives highlight the importance of integrating economic analysis into regulatory decision-making to enhance transparency and policy coherence.

49. Finally, ongoing market studies and continued dialogue with stakeholders remain essential for informing evidence-based interventions. By systematically assessing the effects of current regulations on market dynamics, pricing behavior, and consumer access, SRE's work provides a foundation for regulatory modernization that strengthens competition, safeguards public health objectives, and promotes sustainable access to medicines. These efforts illustrate how targeted advocacy and data-driven analysis can help

align Brazil's pharmaceutical policies with broader goals of efficiency, equity, and innovation in healthcare.