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Competition and Regulation in the Healthcare Sector – Note by Brazil

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1. Introduction[1]

1. Access to medicines at affordable prices is a fundamental determinant of public health and economic productivity, yet pharmaceutical markets are structurally prone to market failures that make regulatory intervention indispensable. Information asymmetries between patients, prescribers, and manufacturers, combined with patent-driven exclusivity and high barriers to entry for innovative therapies, routinely give rise to limited competition and significant market power on the part of producers. These structural characteristics reinforce the need for policy framework in which price regulation and competition policy function as complementary, mutually reinforcing instruments.

2. Against this backdrop, the present contribution outlines the competition advocacy initiatives led by the Secretariat for Economic Reforms (SRE)[2] of the Ministry of Finance. The SRE holds a particularly strategic position in pharmaceutical policy, as it occupies a permanent seat on the Drug Market Regulation Chamber (CMED),[3] the interministerial body responsible for defining the regulatory framework of the pharmaceutical market. Section 2 describes Brazil's pharmaceutical regulatory framework, covering the institutional architecture and principal pricing mechanisms. Section 3 presents an overview of the market's structure and competitive dynamics. Section 4 examines the key policy developments in pharmaceutical regulation, with particular attention to the pro-competitive reforms achieved through the SRE's engagement within CMED. Section 5 details the market studies conducted under the Regulatory and Competition Assessment Procedure (PARC), presenting the findings and recommendations of completed investigations and outlining the two new cases recently selected for in-depth assessment.

2. The Brazilian Pharmaceutical Regulatory Framework

3. Brazil's pharmaceutical regulatory framework integrates health, industrial, and economic dimensions through an interdependent institutional structure. Three principal bodies govern the medicine lifecycle. The Brazilian Health Regulatory Agency (**Anvisa**) is responsible for issuing clinical trials and market authorizations, ensuring the quality, safety and efficacy of drugs, encompassing the conduct of inspections, and post-market surveillance. Marketing authorizations are generally issued for ten-year periods. The **Drug Market Regulation Chamber (CMED)** oversees economic regulation, including the setting of maximum ex-factory and retail prices and minimum mandatory discounts for public procurement. The **National Committee for Health Technology Incorporation (Conitec)** conducts health technology assessments and makes reimbursement decisions for the public health system (SUS). Together, these bodies govern market entry, pricing, and

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[2] Mandated under Law No. 12,529/2011 to promote competition, SRE issues opinions on normative acts and legislative proposals that may impact competition, prepares sectoral studies, and proposes reviews of anticompetitive laws and regulations.

[3] 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, and the Ministry of Development, Industry, Trade and Services.

incorporation into the public health system, ensuring that medicines meet both public health and economic objectives.

4. CMED sets maximum prices through two principal methodologies. External reference pricing (ERP) benchmarks proposed domestic prices against those observed in a basket of reference countries as well as the product's country of origin. Internal reference pricing (IRP) compares proposed prices with those of identical or therapeutically equivalent medicines already authorized in the Brazilian market. The final approved price corresponds to the lowest value among the applicable ERP and IRP benchmarks and the price proposed by the applicant. Generic medicines are subject to a specific rule, with factory prices capped at 65% of the reference product price. Price ceilings are updated annually based on inflation, a productivity factor (Factor X), inter-sector price alignment (Factor Y), and intra-sector competitiveness (Factor Z), with lower adjustments permitted for more concentrated markets.

5. This regulatory architecture underwent its most significant reform in over two decades with the enactment of Resolution CM/CMED No. 3/2025, which replaced rules that had remained largely unchanged since 2004. The reform introduced targeted structural adjustments to both the ERP and IRP methodologies, including the expansion of the international reference country basket and the introduction of differentiated pricing pathways for biosimilars and incrementally innovative medicines, designed to improve the framework's responsiveness to market realities and to reduce distortions that had accumulated under the previous regime. The specific provisions of this reform and their competition policy implications are examined in detail in Section 4.1.

6. Notwithstanding this progress, a structural limitation of Brazil's price adjustment model remains to be addressed. While the annual update formula provides regulatory predictability, it does not incorporate mechanisms for downward price adjustments, meaning ceilings 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 therapeutically substitutable medicines.

7. Within the Unified Health System (SUS), access to medicines follows a value-based approach led by Conitec, which conducts evidence-based appraisals prior to incorporation, combining clinical efficacy, safety, and economic evaluations such as cost-effectiveness and budget impact analyses. Centralized government procurement of high-cost medicines further strengthens the public sector's bargaining position, particularly in therapeutic segments characterized by high concentration and limited therapeutic alternatives.

3. The Brazilian Pharmaceutical Market

8. Brazil's pharmaceutical market ranks among the largest in Latin America, with industry revenues reaching BRL 160.7 billion (approximately EUR 27.7 billion) in 2024.[4] However, revenue growth has been predominantly price-driven rather than consumption-based. Between 2020 and 2023, industry revenues grew 55%, from BRL 83 billion to BRL 128 billion, while unit sales rose by only 13%. The number of medicine presentations with

[4] Source: Anvisa, Anuário Estatístico do Mercado Farmacêutico 2024. Available at: https://www.gov.br/anvisa/pt-br/centraisdeconteudo/publicacoes/medicamentos/cmed/anuario-estatistico-do-mercado-farmaceutico-2024.pdf/view

a price ceiling above BRL 10,000 (approximately EUR 1,725) more than doubled between 2020 and 2024, rising from 240 to approximately 600, and revenues from these high-cost products tripled over the same period. This pattern reflects a broader global trend toward high-cost innovative therapies and underscores the structural challenge confronting regulators: delivering price discipline in markets where competitive forces alone are insufficient.

9. Over 55% of total Brazilian sector revenues are generated in markets where Herfindahl-Hirschman Index (HHI) values exceed 2,500, a threshold conventionally associated with oligopolistic or monopolistic market structures. In these segments, predominantly comprising innovative medicines, biologicals, and advanced therapies, the lack of therapeutic substitutes severely limits the scope for market-driven price competition, making price-cap regulation the primary mechanism for constraining excessive pricing. Evidence confirms that, in highly concentrated therapeutic classes, transaction prices tend to remain close to regulated ceilings, indicating that the cap, rather than competitive pressure, functions as the binding constraint on pricing behavior.[5]

10. At the same time, competition acts as a powerful driver of price reductions and improved access, particularly in therapeutic classes with a strong presence of generics. Where multiple suppliers compete, market dynamics lead to substantial discounts relative to regulated price ceilings. In Brazil, more than half of all medicines were sold at discounts exceeding 50% between 2021 and 2023.[6]

11. This outcome also reflects limitations in the regulatory framework, which may lose precision over time as an instrument for promoting affordability. The one-directional indexation mechanism – lacking downward price adjustments –, progressively widens the gap between regulated ceilings and effective transaction prices in more competitive market segments. Therefore, price ceilings increasingly reflect historical administrative decisions rather than prevailing market conditions, constraining the regulator's ability to ensure competitive parity across therapeutically equivalent products and reinforcing the role of competition in driving price reductions.

12. This evidence underscores the complementary nature of price regulation and competition policy: the former constrains pricing power where competition is structurally absent, while the latter drives prices toward efficient levels where market conditions permit.

13. Moreover, centralized public procurement has proven to be another effective cost-containment instrument in Brazil's pharmaceutical market. Econometric evidence drawn from an analysis of over two decades of federal government medicine purchases (2000 - 2021) demonstrates that administratively negotiated, large-volume acquisitions are systematically associated with significantly lower unit prices: each 1% increase in the quantity demanded is associated with a 0.17% reduction in the unit price of the procured product.[7]

[5] This topic was extensively examined in Brazil's contribution to the OECD Global Forum on Competition in the Healthcare Sector, held on 1 December 2025 at the OECD headquarters in Paris. Available at: https://one.oecd.org/document/DAF/COMP/GF/WD(2025)16/en/pdf

[6] Source: Procedimento de Avaliação Regulatória e Concorrencial - Resolução CMED nº 02/2004 - Preços de Medicamentos. Available at: https://www.gov.br/fazenda/pt-br/composicao/orgaos/secretaria-de-reformas-economicas/parc/documentos/parc_cmed.pdf/view

[7] De Negri, F., Ribeiro de Mello, C. E., & Mourthe, A. C. L. (2024). *Federal government procurement of medicines over the last two decades*. In F. De Negri, G. F. Zucoloto, P. Koeller, P. Miranda, & T. Chiarini (Eds.), *Technologies and prices in the pharmaceutical market* (Vol. 1). Rio de Janeiro: Instituto de Pesquisa Econômica Aplicada (Ipea). Available at: https://dx.doi.org/10.38116/9786556350806cap4

14. This reflects the bargaining power gains generated by the consolidation of previously fragmented state and municipal procurement into unified federal purchasing volumes: a structural shift progressively implemented within the SUS from the late 2000s onwards, particularly for complex and high-cost therapies. By contrast, judicially mandated purchases, which are characteristically small in volume and conducted outside competitive negotiation channels, were associated with price premia of 30% or more relative to equivalent administratively procured products, underscoring the fiscal cost of pharmaceutical litigation as a parallel, non-competitive acquisition channel. Taken together, these findings reinforce the case for sustained investment in centralized procurement mechanisms as a critical complement to price-cap regulation in therapeutic segments where market concentration and limited therapeutic substitution otherwise constrain the regulator's capacity to discipline pricing behavior (De Negri, Mello and Mourthe, 2024).

4. Key Policy Developments in Brazil's Pharmaceutical Regulation

4.1. Resolution CM/CMED No. 3/2025: A Structural Reform of the Pricing Framework

15. Resolution CM/CMED No. 3/2025, published in December 2025, constitutes the most significant reform to Brazil's pharmaceutical pricing framework in over two decades. The resolution preserves and refines both the ERP and IRP methodologies as the twin pillars of the pricing system, while introducing targeted structural adjustments. Notably, some of these adjustments were directly suggested by competition advocacy conducted by the SRE, both through its engagement as a permanent member of CMED and through the evidence-based market studies carried out under the PARC framework. It illustrates the concrete policy impact that systematic competition assessment can produce when integrated into the regulatory process.

16. Among its most consequential innovations is the **expansion of the international reference basket**. The resolution adds six new jurisdictions: South Africa, Germany, Japan, Mexico, Norway, and the United Kingdom, bringing the total reference basket to 14 countries.[8] The proposed factory price may not exceed the lowest price observed across reference countries, and a definitive price requires demonstrated commercialization in at least four reference jurisdictions. By incorporating markets where lower negotiated prices prevail, including middle-income economies such as Mexico and South Africa, which face pricing pressures more comparable to Brazil's, the updated basket increases the likelihood that international benchmarks will translate into more affordable ceiling prices domestically, particularly for innovative and high-cost therapies.

17. The resolution also formalizes the regulatory treatment of **incremental innovation**, defining it as a modification to an originator medicine arising from genuine innovative activity, explicitly excluding purely cosmetic changes or modifications without sufficient novelty or technological effort. Medicines classified as incrementally innovative, including new associations, routes of administration, concentrations, pharmaceutical forms, and packaging, are recognized as a distinct pricing category calibrated to their degree of added clinical benefit. This framework is noteworthy for its potential to promote quality-based

[8] The basket of reference countries also includes Australia, Canada, Spain, the United States, France, Greece, Italy and Portugal.

competition: by creating differentiated pricing pathways for genuinely improved formulations, the regulation encourages meaningful therapeutic advances rather than superficial product modifications pursued solely for pricing purposes.

18. Two specific reforms were directly influenced by SRE's competition advocacy efforts under PARC. First, regarding **biosimilars**, the study identified that, within the Brazilian private healthcare system, hospitals systematically preferred higher-priced originator biologics over lower-cost biosimilars, not for clinical reasons, but because reimbursement practices between hospitals and private health insurers were typically anchored to regulated ceiling prices. This allowed hospitals to capture the margin between the regulated ceiling price and the effective transaction price as revenue, effectively neutralizing the competitive advantage of biosimilars.

19. The new resolution addresses this by establishing a unified price mechanism for biosimilars (Category 7 medicines) and their reference biological originators. Under this provision, a single factory price is set for both products simultaneously, determined by applying a mandatory 20% discount to the originator's factory price. By introducing a harmonized factory price for both originators and biosimilars, the new regulation removes incentives for reimbursement-based arbitrage and is expected to restore effective price competition in a market segment previously characterized by structurally distorted procurement dynamics.

20. Second, the new resolution revises the **pricing rules for generic medicines**, correcting a significant competitive distortion identified under the previous regulatory framework, where the mechanical linkage between generic and originator prices created perverse entry-deterrence effects: when originator manufacturers strategically reduced their regulated ceiling prices, newly entering generics, constrained to price at no more than 65% of the then-current originator ceiling, faced a compressed and potentially non-viable price floor, raising effective barriers to market entry.

21. Now, article 24 establishes that the permitted factory price for generic medicines may not exceed 65% of the reference medicine's factory price at the time of the generic's market entry, subsequently updated through the annual price adjustment indices applicable to all medicines. Subsequent changes to the originator's factory price do not affect the generic's price ceiling, insulating generic entrants from strategic originator price movements that could otherwise compress their margins and deter entry. As an absolute constraint, the generic's factory price may not exceed the originator's currently permitted ceiling under any circumstances.

22. Notwithstanding these advances, certain structural limitations persist. Brazil's system still lacks mechanisms for downward price adjustments, and discussions remain ongoing regarding the introduction of extraordinary price realignments to better reflect actual market conditions.

4.2. Law No. 15,357/2026: Pro-Competitive Reform in Pharmaceutical Retail

23. A significant pro-competitive reform in pharmaceutical retail was introduced with the enactment of Law No. 15,357 of 20 March 2026, which authorizes the installation of pharmacies and drugstores within supermarket sales areas. Under the new framework, pharmacy operations within supermarkets must occupy a physically delimited, segregated, and exclusive space with appropriate technical and sanitary infrastructure — including climate control, traceability systems, and pharmaceutical care facilities. These units may be operated directly by the supermarket entity or through a contractual arrangement with an already-licensed pharmacy. The presence of a qualified pharmacist during all operating

hours remains mandatory, and the dispensing of prescription and controlled medicines is subject to the full requirements applicable to standalone pharmacies.

24. From a competition policy standpoint, Law No. 15,357/2026 constitutes a meaningful structural reform with the potential to reshape competitive dynamics in pharmaceutical retail. Prior to its enactment, the prohibition on supermarket-based pharmacy operations functioned as a regulatory barrier to entry that effectively shielded incumbent pharmacy chains from a class of potential competitors endowed with substantial commercial infrastructure, purchasing scale, and consumer footfall. The reform enables large supermarket groups to contest market positions previously held by dominant pharmacy chains, while also creating new entry possibilities in smaller municipalities where standalone pharmacy networks face limited competitive pressure and consumers have had few alternatives. The law further authorizes pharmacies installed within supermarkets to engage digital channels and e-commerce platforms for logistics and home delivery — an additional dimension that may amplify the competitive impact of the reform by extending the reach of new entrants beyond their physical store locations.

25. This is particularly relevant because econometric evidence from the Brazilian pharmaceutical retail market demonstrates that the number of competing pharmacy outlets has a direct and quantitatively significant impact on medicine prices. The transition from monopoly to duopoly in local pharmacy markets is associated with statistically significant price reductions: approximately 5% for branded medicines and up to 10% for generics. The entry of a third competitor produces additional, although more moderate, downward pressure on prices.[9]

26. These findings have important implications for the expected welfare effects of Law No. 15,357/2026. By allowing supermarket groups, which already possess substantial purchasing power, established distribution networks, and high consumer traffic, to enter local pharmacy markets, the reform is expected to intensify competitive pressure precisely in those regions and market segments historically characterized by high concentration levels. As a result, the liberalization of entry conditions is likely to translate into tangible reductions in retail medicine prices and improved consumer access.

5. Competition Advocacy through Market Studies: The PARC Framework

27. In addition to its regulatory engagement within CMED, the SRE conducted market studies to assess the competitive effects of pharmaceutical regulation through the Regulatory and Competition Assessment Procedure (PARC).[10] Established under Regulation SRE No. 12/2024, PARC provides a structured mechanism for market participants and stakeholders to identify potentially anticompetitive regulations for review. The process is initiated through public consultations, and the SRE applies the OECD

[9] Ribeiro, E. P., & Gomes, V. *Retail Entry Effects on Pharmaceutical Prices: A View from Large Retail Chains in Brazil*. Available at: https://www.anpec.org.br/encontro/2015/submissao/files_I/i8-42b4e1574c03639f74ca64190c09c6a4.pdf

[10] The PARC framework was established under Regulation SRE No. 12/2024 and provides a structured mechanism for identifying and reviewing potentially anticompetitive regulations through public consultations. The selection of regulations for assessment is based on criteria including public interest, potential competitive impact, and whether a prior competition impact assessment was conducted by the responsible authority.

Competition Assessment Checklist as its primary analytical framework.[11] The following subsections present two completed market studies and two newly initiated investigations.

5.1. Completed Studies

5.1.1. Clone Medicine Registration: Assessment of RDC No. 954/2024

28. In Brazil, the marketing authorization of medicines is governed by Anvisa through a set of resolutions and normative instructions establishing the quality, safety, and efficacy requirements that applicants must demonstrate via technical and clinical dossiers. While essential to public health protection, these processes are resource-intensive and time-consuming, and can function as regulatory barriers to market entry.

29. To mitigate this tension, Article 41 of Law No. 9,782/1999 expressly authorizes Anvisa to simplify registration procedures where doing so does not compromise public health oversight. Under this mandate, the agency has developed a range of prioritization and simplification measures, including a streamlined pathway for "clone medicines", medicines whose technical and clinical documentation has already been evaluated and approved in connection with an existing reference registration.

30. "Clone medicines", or duplicate product, means a medicinal product that is identical to the master product with respect to its technical and regulatory characteristics, including manufacturer, manufacturing process, composition, dosage form, and strengths, differing only in commercial attributes such as trade name, labeling, and package leaflet, and whose application relies on the documentation previously submitted for the master product under a simplified review pathway. While "Master product" means the medicinal product whose registration or post-approval application is subject to the ordinary regulatory pathway, requiring the full submission of administrative and technical-scientific documentation relating to quality, safety, and efficacy, in accordance with the applicable regulatory requirements.

31. In December 2024, Anvisa published Resolution RDC No. 954/2024, which introduced a significant restriction to Brazil's simplified registration procedure for clone medicines. Under the previous framework (RDC No. 31/2014), any company could access the simplified procedure through contractual arrangements with the master product registration holder, reducing registration timelines from the standard two-to-three years required for the ordinary procedure to between two and six months. The 2024 resolution restricted eligibility exclusively to companies belonging to the same economic group as the master holder, effectively foreclosing third-party partners that had historically used the procedure under commercial licensing and supply agreements.

32. The SRE's competitive assessment identified significant anticompetitive risks. Data from 2021 to 2024 indicate that clone medicines accounted for approximately 48% of all annual registration applications submitted to Anvisa, with an average of 26% filed by companies outside the master product holder's economic group, a segment now effectively excluded from the simplified pathway. The restriction was found to: (i) reduce the number and variety of suppliers capable of bringing identical medicines to market; (ii) significantly increase market entry costs for excluded firms; (iii) and raise production costs asymmetrically in favor of incumbent groups. Clone medicines registered by distinct economic groups, predominantly generics, were consistently sold at deeper discounts

[11] 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.

relative to regulated ceiling prices than clones registered within the same economic group, confirming their stronger contribution to competitive dynamics and affordability.

33. While acknowledging Anvisa's legitimate public health concerns, the SRE concluded that the restriction is disproportionate, as existing regulatory safeguards — including mandatory dossier access obligations, a 30-day post-registration alignment deadline, and Anvisa's power to audit and cancel clone registrations — are already sufficient to address the identified risks without a blanket exclusion based on corporate structure. The SRE accordingly recommended that Anvisa revise Article 2 of RDC No. 954/2024 to restore access for third-party companies, complemented by a reinforced declaration of dossier delivery signed by the responsible officers of both the master product and clone holders — a targeted and less restrictive measure preserving both public health safeguards and the competitive benefits of a more open registration pathway.

5.1.2. Pricing Framework for Newly Approved Medicines: Assessment of CMED Resolution No. 2/2004

34. The second completed market study, previously discussed at section 4.1., assessed the competitive implications of CMED Resolution No. 2/2004, which establishes the criteria for defining medicine price ceilings in Brazil. The analysis identified that, while the price-cap system plays a critical role in ensuring access in highly concentrated markets, its design has generated unintended competitive distortions. In particular, the study found that the coexistence of different price ceilings for therapeutically equivalent medicines, differing by up to 80% solely due to differences in market entry dates or the identity of the manufacturer holding the marketing authorization, creates artificial competitive advantages unrelated to quality or therapeutic merit.

35. This structural asymmetry would amount to little more than a regulatory curiosity were it not for the pronounced competitive distortions it generates in hospital procurement and private health insurance markets, where reimbursement practices are systematically anchored to regulated ceiling prices. In these segments, providers are thereby incentivized to procure higher-ceiling products on economic grounds, capturing the margin between the regulated ceiling and the actual transaction price as revenue. The result is a self-reinforcing dynamic that inflates system-wide healthcare costs and fundamentally undermines the pro-competitive rationale of the price regulation framework itself.

36. A second concern relates to the linkage between generic prices and the originator's price ceiling. When the reference product's holder requests a reduction in its maximum authorized price, new generics entering the market become subject to even lower price caps, a mechanism that, paradoxically, may function as a barrier to entry by compressing entrant margins below commercially viable levels.

37. The SRE recommended a set of pro-competitive reforms, including the introduction of periodic and rule-based price reviews to align ceilings with market conditions, the reduction of price asymmetries across equivalent products, and the revision of the generic-to-reference price linkage to prevent entry deterrence. As discussed at section 4.2. these findings directly influenced several provisions of Resolution CM/CMED No. 3/2025, illustrating the concrete policy impact of the PARC framework.

5.2. Ongoing Investigations

38. Building on the momentum of its first advocacy cycle, on 25 March 2026 the SRE selected two additional cases for in-depth competition assessment within the pharmaceutical sector. The selection of these cases was guided by prioritization criteria

consistent with OECD best practices, including the economic relevance and public interest of the regulated sectors, the potential magnitude of identified competitive distortions, and the extent to which the regulatory bodies responsible conducted prior competition impact assessments before the relevant instruments were adopted.

5.2.1. Registration, Importation, and Quality Control of Radiopharmaceuticals (ANVISA RDC No. 738/2022)

39. This investigation was initiated following a representation submitted by the National Association of Nuclear Medicine Companies (ANAEMN), raising concerns about significant competitive distortions in the Brazilian radiopharmaceuticals market arising from recent regulatory developments. According to the submission, successive regulatory changes following the constitutional amendment opening of the sector have, in practice, led to a re-concentration of supply, replacing a former public monopoly with a highly concentrated private structure, with market concentration exceeding 90% in certain segments. The representation documents evidence of substantial price increases and restrictive commercial practices that may limit access to essential inputs for diagnostic and therapeutic procedures, contributing to supply shortages, delayed medical procedures, and adverse effects on patients, particularly in underserved regions.

40. The SRE will assess whether the regulatory framework governing the production and distribution of radiopharmaceuticals constitutes a barrier to entry, and, if necessary, will propose reforms to restore competitive conditions, improve supply reliability, and ensure equitable access to critical healthcare services.

5.2.2. Remote and Online Dispensing of Medicines (ANVISA RDC No. 44/2009)

41. This investigation responds to a representation submitted by the Brazilian Chamber of the Digital Economy, which alleges that specific provisions of ANVISA RDC No. 44/2009 impose disproportionate restrictions on the remote dispensation of medicines, and may generate anticompetitive effects in pharmaceutical retail. In particular, the representation argues that the requirement that online sales be tied to a physical pharmacy open to the public, combined with limitations on the use of third-party digital platforms and centralized logistics, is argued to increase entry costs, restrict the scalability of digital business models, and disadvantage small and medium-sized pharmacies. According to the complainant, these alleged constraints are seen as reinforcing the market position of large vertically integrated retail chains, limiting competitive pressure, and reducing the efficiency gains associated with e-commerce and digital distribution.

42. The SRE will assess whether the existing regulatory framework unnecessarily restricts the development of digital pharmaceutical distribution channels, and, if necessary, will identify reforms to promote regulatory modernization and more competitive, accessible dispensation models — with particular attention to their implications for access in underserved and remote regions.

6. Conclusion

43. Brazil's experience in the pharmaceutical sector offers a concrete illustration of how competition advocacy, when systematically embedded within regulatory institutions, can translate evidence-based analysis into measurable policy outcomes. The reforms described in this contribution, spanning pricing regulation, market entry, and procurement, collectively reflect a coherent strategy premised on the complementarity of price regulation

and competition policy, and on the recognition that neither instrument alone is sufficient to ensure affordability and access across a market as structurally heterogeneous as Brazil's pharmaceutical sector.

44. The most significant achievements have come through the SRE's dual institutional positioning. As a permanent member of CMED, the SRE has been able to bring competition analysis directly to bear on pricing policy decisions, contributing to the enactment of Resolution CM/CMED No. 3/2025 — which corrects long-standing distortions in biosimilar pricing and generic medicine entry conditions, expands the international reference basket, and formalizes incentives for genuine incremental innovation. Through PARC, the SRE has produced rigorous market studies that identified anticompetitive effects of specific regulatory provisions and proposed proportionate alternatives, with findings that directly informed the content of the 2025 pricing reform.

45. Nonetheless, important challenges remain. The absence of downward price adjustment mechanisms continues to limit the regulator's capacity to respond to falling international reference prices or declining production costs, progressively widening the gap between regulated ceilings and effective transaction values in competitive segments. The two ongoing PARC investigations, covering radiopharmaceuticals and online medicine dispensing, address emerging frontiers where regulatory design may be constraining competition and access.

46. More broadly, Brazil's experience underscores a lesson of wider relevance: in pharmaceutical markets, where structural concentration, information asymmetries, and regulatory complexity interact, the greatest gains in affordability and access are likely to come not from competition policy or price regulation pursued in isolation, but from institutional arrangements that enable both to be designed and applied in a mutually reinforcing manner.