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Competition and Regulation in the Healthcare Sector – Note by Chile

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1. Introduction

1. Healthcare has long been a central area of Chile's competition policy agenda, particularly for the country's competition authority, the FNE[1]. Its importance is both social and economic and the markets involved present distinctive analytical challenges. Healthcare is not a single market, but a set of connected markets shaped by dense regulation, strong information asymmetries, fragmented decision-making and an extensive public presence[2]. These conditions create persistent risks of weak competition, while also limiting the extent to which conduct enforcement alone can effectively address the underlying problems.

2. Chile's healthcare system combines public and private actors in financing, service provision and the production, distribution and dispensing of medicines. On the financing side, a mandatory 7% income contribution is allocated either to the public insurer, *Fondo Nacional de Salud* ("Fonasa"), or to private insurers, the *Instituciones de Salud Previsional* ("*Isapres*"). Fonasa covers around the 86% of the population and finances care within the public network, while also allowing access to private providers under certain modalities. Isapres offer regulated plans for private care, frequently supplemented by voluntary complementary coverage. Service provision is similarly divided across levels and actors: primary, secondary and tertiary care within the public network coexist with private clinics and medical centres. Medicines and medical inputs constitute a further market segment, in which public procurement is heavily mediated by the *Central de Abastecimiento del Sistema Nacional de Servicios de Salud* ("CENABAST")[3], while private wholesalers and pharmacy chains remain central to retail distribution.

3. This institutional architecture pursues legitimate public objectives, including access, financial protection, quality and patient safety. It also has direct implications for competition. The coexistence of different regulatory regimes, payers and purchasers; the separation between prescribing, purchasing and consumption decisions; and the interaction between sanitary regulation and patent protection all affect how competitive pressure arises and whether it translates into lower prices, better quality or innovation.

4. These tensions are particularly visible in pharmaceutical markets. Chile's experience shows that formal entry and the presence of multiple suppliers do not necessarily generate effective price competition. In other words, incentives are shaped not only by the number of firms, but also by sanitary registration, bioequivalence rules, prescribing and dispensing practices, pharmacy operation, procurement design and patent protection. For that reason, Chilean competition policy in this sector has increasingly

[1] As contextual background, it is relevant to note that Chile's institutional framework for competition law enforcement is characterized by a bifurcated model, with a clear separation between the investigative and prosecutorial body—the FNE, which is also responsible for merger assessment and holds statutory powers to promote competition—and the adjudicative or judicial body—the *Tribunal de Defensa de la Libre Competencia* (Competition Tribunal or TDLC). The Supreme Court of Justice also plays a role within this institutional framework, acting as the appellate body that reviews TDLC's decisions.

[2] FNE, *Market Study on Pharmaceuticals (EM03-2018)*, Final Report (January 2020). Available at: link [last accessed: May 2026].

[3] CENABAST plays a particularly important role as a pooled public purchaser for the health system and, under more recent reforms, also as a channel through which certain private pharmacies may access centrally procured medicines under regulated conditions.

combined different kinds of enforcement with advocacy, market studies[4] and ex post evaluation[5].

5. In fact, the FNE's work in healthcare has drawn on nearly the full range of competition-policy tools. Cartel enforcement has been especially important. In the *Pharmacies* case, the FNE uncovered a nationwide price-fixing scheme among the three largest pharmacy chains, which led to what were then record fines and helped prompt the 2009 amendment to the Competition Act[6]. In *Ampoules,* the FNE uncovered a long-running cartel affecting tenders for injectable medicines and the case became an important precedent on the notion of a single and continuous agreement[7]. The *Saline* case likewise involved collusion in public tenders for saline solution[8].

6. The FNE has also pursued collusive conduct among specialist physicians. Cases such as *AM Patagonia, Ñuble Gynecologists* and *Valparaíso Surgeons* involved groups of doctors coordinating fee schedules and bargaining collectively with health insurers[9]. More recently, *Medical Gases,* which remains pending before the *Tribunal de Defensa de la Libre Competencia* (Competition Tribunal or "TDLC"), concerns an alleged customer-allocation agreement between the two main producers of medical gases. That case is particularly notable for the breadth of the FNE's investigative tools— leniency, wiretaps, dawn raids and seizures—and because the fines requested are among the highest ever sought in Chile[10].

7. Beyond cartels, the FNE has also intervened against unilateral conduct. A leading example is *Searle,* where the authority challenged evergreening practices based on a secondary patent over Celecoxib. The 2016 settlement opened the market through broad, royalty-free licensing commitments[11]. According to FNE's recent ex post assessment,

[4] FNE, *Market Study on Pharmaceuticals (EM03-2018)*, Final Report (January 2020). Available at: link [last accessed: May 2026].

[5] FNE, *Impact Assessment: FNE Intervention in the Celecoxib Market (EI02-2026)* (January 2026). Available at:link [last accessed: May 2026].

[6] FNE, press release "*Supreme Court upholds the TDLC's ruling and imposes the maximum fine on Farmacias Cruz Verde S.A. and Salcobrand S.A. in the collusion case*" (7 September 2012). Available at: link [last accessed: May 2026]. See TDLC, Ruling No. 119/2012. Available at: link. See also Supreme Court, Case No. 2578-2012. Available at: link [last accessed: may 2026].

[7] FNE, press release "*Supreme Court Convicts Sanderson and Fresenius Laboratories for Collusion in Public Pharmaceutical Tenders, with Total Fines of USD 15 Million*" (27 January 2020). Available at: link. See TDLC, Ruling No. 165/2018. Available at: link. See also Supreme Court, Case No. 278-2019. Available at: link [last accessed: may 2026].

[8] FNE, press release "*Supreme Court Upholds TDLC Decision and Confirms Sanction against Baxter for Collusion in Public Tenders for Saline Solution*" (17 October 2020). Available at: link [last accessed: May 2026]. See TDLC, Ruling No. 172/2020. Available at: link. See also Supreme Court, Case No. 16.986-2020. Available at: link [last accessed: may 2026].

[9] FNE, press release "*Supreme Court Orders the Dissolution of the Association Grouping Ñuble Gynecologists and Confirms Collusion Fines against 25 Specialists*" (7 January 2016). Available at: link [last accessed: May 2026]. See TDLC, Ruling No. 145/2015. Available at: link. See also Supreme Court, Case No. 5609-2015. Available at: link [last accessed: may 2026]. See also FNE, press release "*The FNE reaches an agreement with 111 surgeons in the Valparaíso region and their professional association*" (17 April 2019). Available at: link [last accessed: May 2026].

[10] FNE, press release "*NE Files Charges against Indura and Linde for Collusion in the Industrial, Medical and Special Gases Market and Requests that the TDLC Impose Total Fines of USD 313 Million*" (6 May 2024). Available at: link [last accessed: May 2026]. See FNE Complaint filed. Available at: link [last accessed: may 2026].

[11] FNE, press release "TDLC Approves Settlement Agreement between the FNE and G.D. Searle LLC Promoting Competitor Participation in the Market for Medicines Containing Celecoxib" (10 November 2016).

public procurement prices fell by about 96%, generating estimated savings of between USD 208 million and USD 546 million over the period analyzed, while also enabling the timely entry of several generic suppliers[12].

8. In merger control, the FNE has blocked two major healthcare transactions: *Redinterclínica / Clínica Iquique* (2019)[13], which would have created a private hospital monopoly in Iquique and *Nexus / Colmena* (2022)[14], a merger between the fourth- and fifth-largest Isapres in a market characterized by high entry barriers.

9. These enforcement efforts have been complemented by advocacy, most notably through the *Market Study on Pharmaceuticals* (2020), which identified competition problems throughout the value chain and resulted in a set of recommendations aimed at speeding up the entry of bioequivalent medicines, improving prescribing and dispensing practices and making public procurement more efficient.

10. Overall, the FNE has pursued an active competition policy in healthcare, with a particular focus on consumer welfare, more effective public purchasing and the removal of structural and regulatory barriers to competition.

11. This contribution describes Chile's recent experience in that field, but from a regulatory perspective. It first reviews the main regulatory and policy developments affecting competition in healthcare. It then discusses the analytical work carried out by the FNE, with particular emphasis on the Market Study on Pharmaceuticals and related work. Finally, it examines the impact of that advocacy and selected interventions, and draws lessons on the relationship between competition and regulation in healthcare markets.

2. Policy Developments

2.1. General context: regulation as a necessity and a source of competitive frictions

12. In Chile, as in other jurisdictions, some forms of healthcare regulation are unavoidable. Market failures in the sector are substantial. Patients generally lack the information needed to assess the quality or relative value of treatments and providers. Physicians act as agents for patients, but do not bear the consequences of their prescribing decisions. Insurers, providers, pharmacies and suppliers operate under different incentives. The state, in turn, performs several roles at once: regulator, insurer, purchaser, financier and direct provider.

13. The relevant question is therefore not whether healthcare should be regulated, but how regulation should be designed. The Chilean experience over the last decade shows that regulation can either enable or hinder competition depending on its institutional design. Some reforms have expanded access and reduced entry barriers; others have improved

Available at: link [last accessed: May 2026]. See TDLC, Case C-310-16. Available at: link [last accessed: May 2026].

[12] FNE, *Impact Assessment: FNE Intervention in the Celecoxib Market (EI02-2026)* (January 2026). Available at:link [last accessed: May 2026].

[13] FNE, Prohibition Report, Rol FNE F178-2019, "*Acquisition of control over Clínica Iquique S.A. by Redinterclínica S.A.*" (9 December 2019). Available at: link [last accessed: May 2026]. See also FNE, Resolution Prohibiting the Transaction, Rol FNE F178-2019 (9 December 2019). Available at: link [last accessed: May 2026].

[14] TDLC, Ruling No. 182/2022, "*Consultation by Nexus Chile SpA regarding a concentration transaction consisting of the potential acquisition of control over Isapre Colmena Golden Cross S.A.*" (20 September 2022). Available at: link [last accessed: May 2026].

transparency or strengthened regulatory capacity. Significant distortions nevertheless remain, especially where regulatory rules have not been adapted to the way competition actually operates in healthcare markets.

14. Against that background, the most relevant developments have been concentrated in five areas: pharmaceutical regulation and bioequivalence; financial protection and access to high-cost medicines; patent protection and regulatory exclusivities; procurement and distribution reforms involving CENABAST; and, more recently, digital health infrastructure.

2.2. Pharmaceutical regulation and the Ley de Fármacos I framework

15. A central development during the period has been the consolidation of the pharmaceutical regulatory framework built around Law No. 20.724, commonly referred to as *Ley de Fármacos I*, together with its implementing regulations[15]. The framework sought to improve competition and access by strengthening the role of bioequivalence, requiring prescribing by International Nonproprietary Name ("**INN**") and imposing obligations on pharmacies regarding the availability and dispensing of bioequivalent products.

16. From a competition-policy perspective, the reform addressed a structural feature of the Chilean pharmaceutical market: even in off-patent markets, medicines often behave not as interchangeable commodities, but as differentiated branded products. Bioequivalence policy was intended to facilitate substitution, create the conditions for stronger price competition and increase confidence among consumers and prescribers that therapeutic alternatives are genuinely interchangeable[16].

17. The competitive success of such a policy, however, depends on more than the formal existence of bioequivalence certification. It also requires a broader regulatory and market environment in which substitution can occur in practice. The FNE's *Market Study on Pharmaceuticals* (2020) showed that this had been achieved only partially[17]. The formal framework advanced, but the market continued to display strong brand-based dynamics, agency problems in prescribing, and limited incentives for pharmacies and laboratories to compete on price.

18. Even so, *Ley de Fármacos I* marked a turning point in Chile's approach to medicines regulation. It made competition concerns more visible within pharmaceutical policymaking and laid the groundwork for subsequent FNE advocacy, which identified the limits of the reform and proposed deeper measures.

2.3. Financial protection and access: Ley Ricarte Soto

19. Another important development was Law No. 20.850, better known as *Ley Ricarte Soto*, which created a system of financial protection for high-cost diagnoses and treatments[18]. Its primary objective is not to promote competition, but to ensure access and protect households from catastrophic expenditure. It nevertheless has relevant competition implications.

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[15] Ley de Fármacos I: Law No. 20.724 (2014), amending the Health Code in matters of regulation of pharmacies and medicines. Available at: link [last accessed: May 2026].

[16] FNE. *Study on the Effects of Bioequivalence and the Penetration of Generic Medicines in the Field of Competition* (2013). Available at:link [last accessed: May 2026].

[17] FNE, *Market Study on Pharmaceuticals (EM03-2018)*, Final Report (January 2020). Available at: link [last accessed: May 2026].

[18] Ley Ricarte Soto: Law No. 20.850, creating a financial protection system for high-cost diagnoses and treatments. Available at: link [last accessed: May 2026].

20. First, the law changed the scale and structure of demand for certain high-cost medicines and treatments, reinforcing the role of public institutions in selecting and procuring these products. Second, it made the design of procurement and prioritization mechanisms more consequential for competition and public expenditure. Where a public system finances very expensive treatments, the way it selects products, structures tenders and interacts with suppliers is central to whether the benefits of competition are realized.

21. Ley Ricarte Soto therefore underscored the need for procurement rules that promote competition where possible and for robust technical processes that ensure public purchasing decisions do not unnecessarily reduce rivalry or entrench market power.

2.4. Patent regulation reform

22. The interaction between pharmaceutical innovation, patent regulation and competition has become increasingly prominent in Chile.

23. A relevant regulatory development was the 2021 reform of industrial property legislation[19]. Among other changes, the reform introduced a ceiling on supplementary patent protection for unjustified delays in patent granting and shortened certain procedural timelines. These changes are relevant because, in practice, lengthy or overly expansive exclusivity can delay generic entry beyond what is necessary to preserve incentives for innovation.

24. The Chilean debate in this area has been shaped by concrete cases in which extended exclusivity generated substantial competitive concerns. The best known is the FNE's Celecoxib case, discussed below, which highlighted how secondary patents and associated strategies may delay entry and maintain high prices for extended periods[20]. The lesson for Chile is that patent rules cannot be assessed in isolation from their effects on downstream competition, access and public expenditure.

2.5. CENABAST reform and the widening of access to public procurement channels

25. Law No. 21.198, enacted in 2020, authorized private and municipal pharmacies to purchase medicines through CENABAST[21]. This was a significant pro-competitive reform for two main reasons.

26. First, it widened access to the lower prices associated with centralized public procurement. Second, it reflected one of the core ideas that had emerged from the FNE's analytical work: in pharmaceuticals, the structure of purchasing channels strongly affects prices. The FNE's Market Study on Pharmaceuticals found very large price differences across channels and showed that institutional buyers were in a much stronger position than retail pharmacy chains to obtain favorable purchasing conditions.

[19] Industrial property reform: Law No. 21.355 (2021), amending the Industrial Property Law and the law establishing the National Institute of Industrial Property (INAPI). Available at: link [last accessed: May 2026].

[20] FNE, *Impact Assessment: FNE Intervention in the Celecoxib Market (EI02-2026)* (January 2026). Available at:link [last accessed: May 2026].

[21] CENABAST reform: Law No. 21.198 (2020), amending the functions of CENABAST and allowing it to intermediate medicines for private pharmacies, pharmaceutical warehouses, and non-profit health establishments under the conditions established by law. Available at:link [last accessed: May 2026].

2.6. Reliance Mechanisms in Pharmaceutical Registration

1. A further relevant policy development was the 2020 amendment to the Pharmaceutical Products Regulation, which introduced an accelerated registration procedure for non-biological medicines already registered by high-surveillance regulatory agencies[22]. Under the new regulations, applicants may rely on a prior authorization granted for the same therapeutic indication, submit the same supporting dossier filed abroad together with the pharmaceutical product certificate and benefit from an accelerated review that, absent requests for clarification, may not exceed three months.
2. The reform also provides for recognition of prior certifications such as good manufacturing practices and bioequivalence. Importantly, the Public Health Institute (known as "**ISP**") clarified that this mechanism does not waive substantive registration requirements; rather, it allows the ISP to take into account what has already been assessed by the reference authority. From a competition perspective, this reform is relevant because it reduces time-to-market for certain medicines already vetted abroad and is broadly consistent with the FNE's Market Study recommendation to create a faster registration pathway for medicines already marketed in other jurisdictions.

2.7. Digital health infrastructure and the move toward electronic prescription

27. Digital health regulation has become a more visible area of reform in recent years. Law No. 21.541, enacted in 2023[23], codified the provision of healthcare services through telemedicine, clarifying the legal framework for remote delivery. In parallel, Chile has rolled out the national electronic prescription system, with broad mandatory application from December 2025[24].

28. These reforms are relevant for competition because they affect entry, switching and the ability to redesign healthcare delivery. In pharmaceuticals, electronic prescription is especially relevant. The FNE recommended the creation of a mandatory national prescription system connected to all pharmacies, precisely because prescribing by INN for interchangeable medicines would otherwise be difficult to monitor and enforce. A mandatory digital prescription system can facilitate standardization, reduce prescribing inertia, improve monitoring of compliance and support substitution mechanisms.

29. The same logic applies to telemedicine more broadly. Digital health can lower geographic barriers, improve matching between patients and providers, and facilitate competition across service modalities. The effect, however, is not automatic. It depends on whether digital infrastructure is designed as an open and neutral platform, or instead as a restrictive layer that reinforces incumbency. Chile's recent reforms therefore represent progress, but not the end of the discussion. Interoperability of records, portability of data and the adaptation of older rules to digital channels remain important unfinished tasks.

[22] Reliance reform / accelerated registration: Supreme Decree No. 54 of 2020, Ministry of Health, amending Supreme Decree No. 3 of 2010 and introducing accelerated registration pathways for certain pharmaceutical products previously authorized by high-surveillance regulatory authorities. Available at: link [last accessed: May 2026].

[23] Telemedicine Law: Law No. 21.541 (2023), allowing healthcare providers to deliver services remotely or through telemedicine. Available at: link [last accessed: May 2026].

[24] Electronic prescription regulation: Decree No. 11 of 2023, Ministry of Health, amending Supreme Decree No. 466 of 1984 approving the Regulation on Pharmacies, Drugstores, Pharmaceutical Warehouses, First-Aid Kits, and Authorized Deposits. Available at: link [last accessed: May 2026].

2.8. Pending and incomplete reforms

30. The clearest example of an incomplete reform process is *Ley de Fármacos II*[25]. Several recommendations from the FNE's pharmaceutical market study were incorporated into the legislative debate around that bill, including measures aimed at facilitating substitution, improving transparency and reducing the scope for brand-based competition to persist despite bioequivalence. The bill, however, faced significant political and legislative difficulties and is currently stalled.

3. Market Studies and Investigations

3.1. The Market Study on Pharmaceuticals

31. The FNE's Market Study on Pharmaceuticals, launched in 2018 and published in final form in January 2020, is the most comprehensive competition-advocacy exercise Chile has undertaken in healthcare[26]. Its scope was unusual by domestic standards and substantial from a comparative perspective.

32. The study covered the full pharmaceutical chain, from production and entry to distribution, retail pharmacy competition and public procurement. It relied on an unprecedented dataset, including detailed information from 27 laboratories accounting for more than 70% of sales through large pharmacy chains, information from three large wholesalers together with summary information from more than 100 smaller ones, data from pharmacy chains, a sample of private institutional healthcare providers, public procurement data, a consumer survey conducted in more than 300 pharmacies, a physician survey and an FNE survey of medical sales representatives. This allowed the FNE to complement descriptive analysis with econometric and behavioral evidence.

33. The study's core finding was that competition in Chile's off-patent pharmaceutical market was not taking place primarily on price. Instead, the market behaved as a differentiated-product market organized around brands, promotion and prescribing habits. In the large pharmacy-chain channel, laboratories competed through marketing and medical promotion, while pharmacies competed mainly through logistics and location. The expected transition toward commodity-like competition driven by bioequivalence had not materialized.

34. This finding challenged a common assumption: that introducing more generics or certifying bioequivalence would be sufficient to generate effective price rivalry. The study showed that formal interchangeability does not automatically become economic interchangeability.

35. The FNE identified several reasons for this outcome. A central factor was the agency problem in prescribing. Physicians choose medicines, but do not bear their cost. Patients bear the cost but typically follow prescriptions and have limited ability or incentive to compare alternatives. Pharmacies, in turn, face incentives shaped by margins and by the need to stock a broad range of branded products because patients often arrive asking for a specific name rather than a therapeutic alternative.

[25] Ley de Fármacos II Bill: Bill No. 9914-11, Bill amending the Health Code to regulate generic bioequivalent medicines and prevent vertical integration between laboratories and pharmacies. Cámara de Diputadas y Diputados de Chile. Available at: link [last accessed: May 2026].

[26] FNE, *Market Study on Pharmaceuticals (EM03-2018)*, Final Report (January 2020). Available at: link [last accessed: May 2026].

36. Information problems compounded these distortions. The study found weak market-wide production and dissemination of neutral information, limited confidence in bioequivalence among some physicians and medical representatives, and a regulatory framework that had not effectively changed market conduct despite seeking to empower consumers. In that environment, firms had strong incentives to continue differentiating products and preserving brand loyalty.

37. The study also produced striking evidence on pricing across channels. Large pharmacy chains were found to pay, on average, approximately 70% more than public-sector buyers and 60% more than private institutional buyers for identical products at comparable purchase volumes. The implication was that the same medicine could circulate under very different purchasing conditions depending on the channel, and that retail market structure and incentives were a key part of the pricing problem.

38. The analysis further identified regulatory barriers along the value chain. These included delays and opacity in sanitary registration and bioequivalence certification; the absence of a sufficiently expedited route for medicines already approved by trusted foreign agencies; lack of transparency on patent status; restrictions on over-the-counter sales outside pharmacies; ambiguity around online dispensing; and fragmented, insufficiently regulated medicine-selection processes in the public sector. The study also found that only a minority of public-sector purchasing, measured by value, was carried out through genuinely competitive tenders, with the remainder relying heavily on direct award.

39. Based on that diagnosis, the FNE proposed a package of fifteen measures. They can be grouped around four objectives.

40. The first objective was to make entry easier and faster. This included improving sanitary registration and bioequivalence procedures, creating more streamlined paths for medicines already approved abroad, strengthening the institutional capacity of the medicine's agency, (*Agencia Nacional de Medicamentos*) and increasing transparency on patents and product status.

41. The second objective was to make substitution effective in practice. This required more than formal prescribing by INN. It required a system capable of ensuring that INN-based prescribing actually changed behavior. The study therefore proposed a national prescribing system and obligations designed to reduce the role of brand names where medicines were therapeutically interchangeable.

42. The third objective was to realign pharmacy incentives so that retail competition would operate more strongly through prices rather than through catalogue breadth and brand stocking. These included proposals concerning how pharmacies dispense medicines and how their remuneration should be structured.

43. The fourth objective was to improve public procurement, including better regulation of medicine-selection processes and clearer, more transparent criteria in public purchasing institutions.

44. The FNE estimated that implementation of the recommendations could generate substantial price reductions in the affected products. More broadly, the recommendations sought to change the market's incentive structure, not merely to correct isolated procedural defects.

3.2. The Celecoxib Case

45. The Celecoxib case provides the clearest Chilean example of the gains that can result when competition is restored in a pharmaceutical market.

46. The case originated in the FNE's investigation into conduct by G.D. Searle LLC, a Pfizer subsidiary, in connection with pharmaceutical products containing the active ingredient celecoxib[27]. The authority concluded that a strategy involving a secondary patent had the effect of artificially extending monopoly conditions beyond the expiry of the original patent, delaying generic entry for many years.

47. In 2016, the matter was resolved through a settlement approved by the Competition Tribunal[28]. The commitments allowed current and potential competitors to enter the market and prevented enforcement of the secondary patent in ways that would continue to block rivalry.

48. The FNE's recent ex post assessment is striking[29]. In the public procurement channel, prices fell by roughly 96% after the market opened to competition and cumulative savings over the evaluation period were estimated between USD 208 million and USD 546 million over the period analyzed, while also enabling the timely entry of several generic suppliers. The case also showed the value of timely intervention: rather than waiting until the natural expiry of the contested exclusivity in 2029, competition was restored much earlier.

49. Celecoxib matters not only because of the magnitude of the savings. It also illustrates a broader point about the relationship between regulation and competition. The competitive problem did not arise from a cartel or a refusal to deal. It emerged from the interaction between patent law, regulatory processes and the strategic use of legal rights. That is precisely the kind of problem that requires a competition authority to engage with the design and effects of regulation, rather than limiting itself to a narrow conception of market conduct.

4. Competition Advocacy and Impact

50. The influence of the FNE's work in healthcare has been most visible in the regulatory and policy sphere.

51. In pharmaceuticals, the *Market Study on Pharmaceuticals* helped reorganize the policy discussion around a coherent competition framework. It connected problems of sanitary registration, bioequivalence, prescribing, dispensing, pharmacy incentives, patent transparency and public procurement and translated that diagnosis into a package of fifteen regulatory recommendations. That influence can be seen, first, in the debate on *Ley de Fármacos II*, where several of the study's proposals were taken up even though the bill ultimately stalled.

52. Second, some reforms adopted outside that bill moved in the same direction as the FNE's recommendations. First of all, in line with the study's recommendations, bioequivalence policy has been implemented at a faster pace in recent years, which means that today a large share of the active ingredients administered orally are subject to bioequivalence requirements. Additionally, in the public channel, policies have been

[27] FNE, press release, "*FNE Files Complaint for Abuse of Dominance against Pharmaceutical Company G.D. Searle LLC, a Pfizer Affiliate*" (9 June 2016). Available at: link [last accessed: May 2026]. See FNE Complaint filed. Available at: link [last accessed: may 2026].

[28] TDLC, settlement agreement approved in Case C-310-16 (Searle/Celecoxib), available at: link [last accessed: May 2026].

[29] FNE, *Impact Assessment: FNE Intervention in the Celecoxib Market (EI02-2026)* (January 2026). Available at:link [last accessed: May 2026].

adopted that have effectively tended to increase the percentage of medicines procured through CENABAST, rather than through individual hospitals, in line with the FNE's finding that prices through the former's tender processes were substantially lower. Moreover, law No. 21.198, which authorized private and municipal pharmacies to purchase through CENABAST, reflected the study's insight that purchasing channels have major competitive consequences in pharmaceutical markets. Likewise, later regulatory changes introducing accelerated registration pathways were broadly consistent with the FNE's concern with faster entry and more effective substitution in practice.

53. A further important precedent was the Celecoxib case. It showed that patent-related strategies, in particular the use of a secondary patent to prolong exclusivity, may operate as significant barriers to entry in pharmaceutical markets.

54. At the same time, Chile's experience also shows the limits of competition advocacy. Some substantial recommendations that resulted from the pharmaceutical market study remain pending, especially those aimed at making substitution effective at the point of dispensing and at realigning pharmacy incentives more fundamentally.

5. Conclusion

55. Chile's experience confirms that competition policy has a meaningful role to play in healthcare, but that this role must be adapted to the sector's institutional realities. In healthcare, regulation is indispensable. Its design, however, can either enable or hinder competition. The central challenge is therefore not to replace regulation with markets, but to ensure that regulation pursues access, quality and safety without unnecessarily insulating market participants from competitive pressure.

56. Over the last decade, Chile has advanced in that direction through targeted reforms, competition advocacy and selective interventions with measurable effects. The pharmaceutical sector is the clearest example. The FNE's *Market Study on Pharmaceuticals* showed that persistent high prices and weak rivalry could not be explained only by concentration or by lack of formal entry. They reflected a deeper set of institutional frictions involving prescribing, dispensing, information, procurement, sanitary regulation and patents. The response therefore had to be equally broad.

57. Chile's progress has been real and significant, but incomplete. Some recommendations have influenced legislation or administrative reform; others remain pending. Ex post evidence shows that well-designed interventions can generate substantial gains, as in the case of municipal pharmacies and especially Celecoxib. The same evidence also shows that incumbents do not always respond to reform in ways that produce strong competitive discipline unless the institutional design is carefully aligned with that objective.

58. For Chile, the main lesson is that healthcare competition policy must be persistent, evidence-based and structurally oriented. The most important contribution a competition authority can make is often not limited to sanctioning unlawful conduct. It also includes identifying the mechanisms through which regulation, incentives and market design interact to shape outcomes. That has been the guiding logic of the FNE's work in healthcare, and it will remain central as Chile continues to refine its regulatory and competition framework in the sector.