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Executive Summary

Efficiency in the Management of Procurement and Inventory in Hospitals

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On March 15, 2023, through Official Letter No. 445, the President of the Republic, Gabriel Boric Font, tasked the National Commission for Evaluation and Productivity (CNEP) with a study to analyze the efficiency of procurement and inventory management processes in the public hospital health network, focusing on pharmaceuticals and medical devices.¹

This stems from the need to ensure greater healthcare effectiveness² in procuring clinical supplies while aiming to increase spending efficiency, given its impact on fiscal expenditure. Between 2018 and 2023, the annual spending on pharmaceuticals and medical devices for hospitals averaged 2% of the central government's operational³ budget. In 2023, this expenditure amounted to approximately 1.4 trillion pesos (USD 1.5 billion), representing 25% of the central government's spending on goods and services.

It is important to highlight that this expenditure has seen significant growth, outpacing other relevant variables such as the increase in the serviced population and overall operational spending. Notably, the proportion of people aged over 60 has grown substantially. Between 2018 and 2023, the real-term expenditure on pharmaceuticals and medical devices increased by 23%.⁴ During the same period, the number of FONASA beneficiaries grew by 15%, the proportion of individuals over 60 years of age rose from 16.6% to 19.2%, and the central government's operational spending increased by 19%.⁵

On the other hand, reported hospital losses of these supplies do not accurately reflect the actual loss, as they are estimates, and consider only pharmaceuticals, excluding medical devices. These devices can represent up to 60% of annual hospital expenditure. These findings underscore the need to analyze and evaluate the management processes of pharmaceuticals and medical devices in Chilean hospitals, seeking alternatives that ensure

¹ According to the WHO and this study, a medical device is defined as any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent, software, material, or other similar or related article intended by the manufacturer to be used, alone or in combination, on humans for one or more of the following medical purposes: a) Diagnosis, prevention, monitoring, treatment, or alleviation of a disease; b) Diagnosis, monitoring, treatment, alleviation, or compensation of an injury; c) Investigation, replacement, modification, or support of an anatomical structure or physiological process; d) Support or maintenance of vital functions; e) Control of conception; f) Disinfection of medical devices; g) Provision of information through in vitro examination of specimens derived from the human body (WHO, 2017).

² In terms of quality, timely delivery, and better safeguarding of their inventories.

³ This includes the sum of the accruals associated with the following budget categories: personnel expenses (s21); consumption goods and services (s22); social security benefits (s23); current transfers (s24); other current expenses (s26); acquisition of non-financial assets (s29); investment initiatives (s31); and capital transfers (s33).

⁴ Calculated using amounts in constant pesos as of May 2024.

⁵ The population estimate was calculated using the databases of the FONASA Beneficiary Population. For operational expenses, following the previous definition, the *Open Budget* data from DIPRES was used.

greater healthcare effectiveness for an aging population and better optimization of resources allocated to these critical supplies, which substantially influence fiscal spending.

Proper pharmaceutical and medical device management is a fundamental responsibility of health systems. This responsibility goes beyond efficient and effective procurement and encompasses implementing comprehensive supply systems. These systems include several interconnected stages, from selection and procurement to storage, distribution, and rational use. The ultimate goal is to ensure the availability of essential medicines and supplies, guarantee their quality, and provide timely care to patients.

Based on this definition, this document focuses on key stages in the procurement process for pharmaceuticals and medical devices, aiming to optimize each step and identify improvement opportunities to serve as a foundation for public policy recommendations. Specifically, the study examines the continuous process designed to ensure the timely delivery of cost-effective pharmaceuticals and medical devices in hospitals for patient treatment. This process was divided into three sub-processes: **Requirements**, **Procurement Management**, and **Traceability and Logistics Operations**. Within each sub-process, priorities were determined based on insights from interviewees, relevant literature, and supporting evidence. The CNEP's recommendations aim to enhance the efficiency of this continuous process through management changes, regulatory adjustments, and investments in infrastructure and technology. In total, the CNEP proposes 30 recommendations: 8 for **Requirements**, 18 for **Procurement Management**, and 4 for **Traceability and Logistics Operations**. Additionally, in line with the terms of reference, recommendations related to institutional commitments and modifications to performance agreements should be viewed as key indicators for monitoring the management of the proposed alternatives. In this context, some recommendations on implementation and commitments may be considered as a single measure; however, they are presented separately to highlight the importance of both the specific alternative and the process that facilitates its adoption. Furthermore, the study suggests that this effort, or similar initiatives, should focus on high-complexity hospitals, given their significance in overall activity and expenditure on pharmaceuticals and medical devices within the hospital network. Specifically, in 2023, 16 hospitals accounted for 50% of total spending on these supplies, while 32 hospitals represented 75%. However, the recommendations can be applied broadly across the hospital network

Requirements for Pharmaceuticals and Medical Devices

The first chapter examines the requirements stage, focusing on selecting and consolidating the quantities of pharmaceuticals and supplies to be procured to meet hospitals' healthcare demands. Recommendations are proposed to strengthen the management of Pharmacy Committees regarding conflict of interest, justification, and transparency while promoting

evidence-based decision-making. Additionally, measures are suggested to encourage the *packaging*⁶ of hospital activities, aiming to improve procurement planning.

At this stage, the Pharmacy and Therapeutic Assistance Committees in medium—and high-complexity hospitals define and update the hospital's pharmacological arsenal⁷ and medical device⁸ portfolio. Given their roles, these committees' decisions have the potential to significantly influence the efficiency and effectiveness of hospital procurement. Therefore, their institutional framework should promote cost-effectiveness criteria, ensuring that alternatives are properly evaluated on their merits through transparency standards. This would strengthen trust in their decisions and credibility within the clinical team (WHO, 2003).

An analysis of hospital committees' institutional framework in Chile by Yarza (2020) indicates that the 2009 *General Technical Standard No. 113* does not include methodologies, monitoring systems, or standards for transparency and conflict-of-interest management. A similar conclusion is drawn by the WHO (2003) and Collao (2011). This finding underscores the need to improve governance, probity, and transparency regulations, ensuring impartial decision-making. In this context, **Recommendation 1.1** suggests amending the regulatory framework (*Decree 140* of the Ministry of Health) to include mandatory transparency and justification of committee decisions, along with proper conflict-of-interest management.

The committees can fulfill their objectives more effectively if provided with the specific resources and expertise needed to evaluate available technologies. Currently, these committees' evaluations conducted at the hospital level are constrained by their capacity and often duplicate efforts that could be shared across the network. Establishing a centralized *Health Technology Assessment* (HTA)⁹ institution emerges as an alternative to support the committees' work. Such an institution would pool resources for health technology evaluations and enhance the system's capacity to assess available technologies continuously. A

⁶ In the context of this study, *packaging* refers to the creation of a standardized list of pharmaceuticals, medical devices, and other supplies necessary for delivering specific care, considering the patient's diagnoses and complexity. By optimizing hospital activity planning and assessing the facility's existing inventories, packaging enables the identification of actual purchasing requirements, ensuring this information is timely transferred to the procurement process.

⁷ It refers to the set of medications available in a hospital to treat patients. This includes all the drugs the hospital uses for various diseases and treatments, ranging from analgesics to antibiotics or specialized medications.

⁸ It refers to the equipment, instruments, and tools used in the hospital to diagnose, treat, or monitor patients. This includes items ranging from syringes and bandages to more complex equipment such as X-ray machines or MRI scanners.

⁹ The Pan American Health Organization (n.d.) defines it as the systematic process of assessing the properties, effects, and/or impacts of healthcare technology. It should consider medical, social, ethical, and economic dimensions, with its primary objective being to provide information for use in healthcare decision-making.

centralized structure would ensure greater consistency in decision-making across the network and eliminate redundancies in technology assessments.

From this analysis, several recommendations arise:

- **Recommendation 1.2** emphasizes the importance of considering two key aspects when establishing an HTA institution: the degree to which its evaluations are integrated into clinical practice and its independence from political administrations. While creating such an entity may be a lengthy process due to the investment required, international experience demonstrates that these institutions support routine healthcare and play a critical role in evaluating innovative and high-cost treatments for the health system.
- **Recommendations 1.3 and 1.4** propose short-term measures to prioritize health technology evaluations by the Ministry of Health (MINSAL) through competitive public funding.
- **Recommendation 1.5** seeks to align committee decisions and hospital activities with these evaluations by establishing clear institutional commitments to promote their implementation.

The chapter concludes by introducing *packaging healthcare services* to enhance pharmaceutical and medical device requirements planning. This approach reduces unwanted variability in supplies while maintaining healthcare effectiveness. It allows for more accurate estimation of required supplies and better alignment of procurement with hospital schedules. Additionally, this planning enables bulk purchasing, leading to better prices for hospitals while reducing the occurrence of urgent and costly orders. Evidence indicates that its implementation can significantly optimize resource use and reduce inefficiencies in hospital procurement processes.

The chapter concludes by emphasizing the importance of reducing costs and optimizing the use of materials without compromising the quality of healthcare services (Avansino et al., 2013; Marchand et al., 2020; Toor et al., 2022; and Toor et al., 2023). In Chile, Regional Resolution Centers (CRR) are working to consolidate this practice in outpatient surgery. Regarding hospital financing, this practice, based on procurement data, provides valuable information for updating the weights of Diagnosis-Related Groups (DRG), critical parameters for defining hospital care expenditure. Additionally, this approach could support the evaluation of medical technologies if a Health Technology Assessment (HTA) institutional framework were established in the country. In this context, the recommendations presented include implementing a pilot project on packaging to evaluate how healthcare facilities manage resources and select procurement channels for acquiring supplies (**Recommendation 1.6**). **Recommendation 1.7** suggests assessing the results of this pilot to identify the most suitable set of supplies from both a healthcare and budgetary perspective, recognizing that packaging facilitates the planning of hospital purchases. **Recommendation**

1.8 aims to consolidate these practices through institutional agreements, promoting their use as complementary to Coordinated Purchasing and Framework Agreements.

Management of Pharmaceutical and Medical Device Procurement

Following the analysis of the requirements stage, the second chapter delves into optimizing the procurement channels used to acquire pharmaceuticals and medical devices, as established in the Public Procurement Law.¹⁰ This exploration aims to enhance spending efficiency by appropriately using existing channels. Additionally, it seeks to improve the timeliness and completeness of deliveries and optimize reverse logistics¹¹ through modifications to performance agreements and bidding terms. Lastly, it seeks to ensure a minimum standard of healthcare quality in a significant portion of purchases and optimize spending by increasing the coverage of the Health Registry for medical devices. In 2023, medical devices accounted for approximately 60% of hospital expenditures on pharmaceuticals and medical devices, equating to around USD 900 million. However, only 0.018% of these devices were registered with the Public Health Institute (ISP), compared to pharmaceuticals, which had 100% registration. The various procurement methods employed by hospitals for pharmaceuticals and medical devices include public and private Bidding, Framework Agreements, Direct Contracting, and emerging mechanisms such as Agile Procurement and Coordinated Purchasing.

Additionally, Intermediation is a channel through which the National Supply Center (CENABAST) consolidates demand pharmaceuticals and medical devices to conduct bidding processes on behalf of healthcare facilities while also managing the resulting contracts. Due to the large volume of purchases, CENABAST often secures more competitive prices than hospitals could obtain independently, generating approximately USD 130 million in savings.

However, as analyzed in this chapter, the concentration of demand through this channel negatively affects the network's operational continuity, increasing the risk of widespread supply disruptions. In 2023, mediation accounted for 25% of hospital spending on pharmaceuticals and medical devices, making it the second most important procurement channel after Bidding.

While Intermediation's ability to aggregate demand positively impacts spending efficiency, it also creates significant dependence within the network on a single supplier for cross-cutting

¹⁰ Law N° 19.886

¹¹ Reverse logistics is the process of efficiently managing the return of products, materials, or equipment from the end consumer to the manufacturer or point of origin. In the context of this study, reverse logistics is associated with defective supplies, health-related recalls, and exchanges due to the expiration of pharmaceuticals and medical devices.

supplies. Economies of scale¹² and the procurement system¹³ often lead to a single supplier securing a contract that covers multiple hospitals. On average, 97% of hospitals in the network may be linked to a single contract of this type, resulting in considerable dependence and heightened operational risk. In the event of supply disruptions due to public health alerts (e.g., quarantine or recalls), alternative suppliers often lack the short-term capacity to meet the network's demands, which at an institutional level represents about 75% of the pharmaceutical market.¹⁴ To address this issue, **multiple awards** emerge as an alternative to increase the resilience of supplies categorized in this chapter as strategic due to their cross-cutting use across various types of care and numerous establishments. This mechanism could be introduced through modifications to CENABAST's authority as defined in *DFLI* of the Ministry of Health or by utilizing Framework Agreements.

It is important to note that the introduction of multiple awards could result in increased prices. However, these potential price increases must be weighed against the healthcare and economic costs currently caused by the suspension of services due to widespread disruptions in the supply of strategic items.¹⁵ Therefore, conducting a comprehensive study to assess the healthcare consequences and expenditures associated with such events within the hospital network is essential.

In this regard, **Recommendation 2.1** suggests that the Ministry of Health (MINSAL) evaluate the impact of sudden disruptions in the supply of strategic items. Based on the results of this analysis, various alternatives to improve the situation could be considered. One such option, outlined in **Recommendation 2.2**, proposes amending current regulations to grant CENABAST the authority to conduct tenders with multiple awards, thereby increasing supplier options and enhancing the network's resilience.

The study also explores the possibility of reintroducing the *Framework Agreement* for these strategic items through **Recommendation 2.3**, which would create opportunities for multiple suppliers to offer similar products. If evaluations suggest that this channel is the best option for enhancing the network's resilience, **Recommendation 2.4** proposes encouraging Framework Agreements through institutional commitments, similar to the approach used for monitoring the Intermediation channel.

¹² The marginal production costs are very low; therefore, it is always feasible to meet the demand of the hospital network.

¹³ By law, tenders must be awarded to the best offer, outright ruling out the possibility of awarding to more than one bidder unless the first option fails to meet the entire demand, which does not occur due to economies of scale.

¹⁴ No figures for devices have been identified, but it is estimated that their participation must be significant, similar to that of pharmaceuticals.

¹⁵ See, for example, *La Tercera* (2023). "Due to microbiological contamination: ISP orders quarantine of medical supply from Sanderson laboratory."

Beyond the Intermediation channel, the Public Procurement Law provides for *Coordinated Purchasing*, a mechanism through which two or more public entities can aggregate demand and organize joint procurement processes via tendering. Unlike Intermediation, in Coordinated Purchasing, contract management is not delegated to a third party; each hospital manages its contracts, eliminating the commission associated with Intermediation. Evidence suggests that implementing this mechanism could reduce hospital procurement costs by 5% to 30%, yet its use remains limited, accounting for just 5% of hospital tenders.

Recommendation 2.5 suggests identifying pharmaceuticals and medical devices suitable for joint procurement by multiple hospitals through this mechanism to address this. Furthermore, **Recommendation 2.6** proposes establishing institutional commitments to incentivize its broader use. Clinical supply packaging strategies can complement these efforts.

Through **Recommendation 2.7**, the CNEP recommends that standardized templates for pharmaceutical and medical device tenders be developed to create a transparent and standardized framework that provides greater certainty in procurement processes. These templates would facilitate the work of hospital procurement departments and improve bidders' understanding of the conditions and requirements. Aligned with other strategies, **Recommendation 2.8** encourages using these templates through institutional commitments, ensuring that monitoring these commitments aids in effective management.

Evidence indicates that procurement channel strategies and tender templates can be promoted through institutional commitments. Establishing agreements with hospitals is critical to ensuring a minimum level of adoption for measures that improve procurement and inventory management. For example, Intermediation has demonstrated increased procurement efficiency by committing to minimum spending levels via this channel, generating approximately USD 130 million in savings in 2023.¹⁶

This chapter also focuses on managing Intermediation by CENABAST, hospitals' second most utilized procurement channel, accounting for 25% of purchases in 2023. Any improvement in the management of this channel has significant implications for the hospital network. In particular, the chapter addresses the commissions charged and the quality of service in terms of timeliness, completeness, and handling of product recalls or withdrawals.¹⁷ In 2023, pharmaceuticals and medical devices worth a net total of 299.595

¹⁶ Gloss 02.h of the Budget Law states that healthcare facilities must acquire at least 80% of the quantity and 40% of the value of medications from the Essential Medication Basket (CEM) through CENABAST intermediation (DIPRES, 2024). Similar targets have also been established by MINSAL for Health Services through the Management Commitments (COMGES).

¹⁷ There may also be recalls due to shipments containing defective supplies.

billion pesos¹⁸ were distributed through this channel. This includes the 7% commission charged by CENABAST,¹⁹ which translates to approximately 20.971 billion pesos in obligations for healthcare facilities. To ensure spending efficiency for this channel, the chapter calls for an analysis of the commission level, which, at the time of this study, is not determined by a technical mechanism but based on historical criteria. Consequently, **Recommendation 2.9** proposes developing a methodology to estimate the optimal commission rate and those for other CENABAST business lines, emphasizing future updates based on this methodology.

Regarding the quality of service provided through Intermediation, the chapter examines compliance with timeliness and completeness in fulfilling hospital orders. According to the *CENABAST 2023 Annual Report* (CENABAST, 2024), 33% of orders arrive before the scheduled date, while 43% are delayed, with an average delay of 9.1 days. The report also highlights that delivery delays and missing products or units are the primary reasons for communication between hospitals and CENABAST.²⁰

This situation influences hospital behavior, as facilities often resort to alternative procurement methods, such as Bidding or Direct Contracting, to secure backup purchases in response to Intermediation failures. These individual purchases typically result in higher prices compared to Intermediation, reducing the cost efficiency of hospital spending on these supplies.²¹ According to the SICEM system,²² between January and September 2023, approximately \$4 million USD was spent on purchases justified by partial or total failures in Intermediation deliveries.

On the other hand, early distribution exerts pressure on healthcare facilities' already strained storage capacity.²³ Evidence collected by the *Office of the Comptroller General of the Republic (CGR)* suggests that using unauthorized or suboptimal storage areas is a common issue in the public health network.

¹⁸ Amount delivered during 2023 (CENABAST, 2024). According to the interviews conducted, the quantity delivered corresponds to the amount virtually distributed by the Central to the establishments, based on the units available for dispatch as reported by the suppliers.

¹⁹ See CENABAST (2024). In addition, some establishments have outstanding debts related to the commission. Furthermore, there is poor consolidation of these invoices, resulting in very low amounts that make collection difficult.

²⁰ Other reasons mentioned include "changes in demand," "issuance of invoices or accounting documents," "exchange letters," "product defects," and "use and request for platform access credentials."

²¹ The names of these tenders or accompanying documents include phrases such as "in case of missing supplies and medications from CENABAST," "in case of non-compliance by CENABAST," or "in case of non-dispatch by CENABAST." See, for example, Tender ID: 1058085-237-LQ24, Tender ID: 1058085-247-LE24, Tender ID: 2107-134-LE24.

²² The SICEM platform allows healthcare facilities to justify purchases of products from the CEM basket outside of the intermediation process for various reasons, including non-compliance by CENABAST suppliers. This ensures that their performance on indicators required by MINSAL and the budgetary gloss is not affected.

²³ See, for example, Liu et al. (2022), Grout et al. (1993), and Cukierman (1976).

The *High Public Management Performance Agreement* for the leadership of CENABAST includes an indicator for completeness and timeliness of scheduled deliveries, acknowledging the importance of these dimensions in evaluating institutional performance. However, the capacity to effectively track supplier deliveries to healthcare facilities remains low.²⁴ There is no monitoring system to confirm whether the promised quantities match what is delivered nor whether the delivery date aligns with the scheduled date. Currently, the completeness indicator measures the quantity committed for delivery versus what was requested by hospitals.²⁵ In contrast, the more relevant metric would compare what was effectively delivered against what was requested. Similarly, the timeliness indicator measures whether deliveries occur within the scheduled month rather than at a more precise time.

Given the potential repercussions of delayed or incomplete deliveries on hospital procurement planning and considering the high standards required by CENABAST's performance agreement, the CNEP recommends increasing the target for timeliness and completeness compliance. Specifically, **Recommendation 2.10** suggests modifying the performance agreement for CENABAST leadership to optimize the measurement of timeliness and completeness, raising the compliance rate from 92% to 98% in alignment with international standards. Additionally, the chapter recommends enhancing CENABAST's capacity to measure supplier compliance with greater precision and in real-time for the contracts it manages. Recommendations from the Traceability and Logistics Operations chapter provide valuable guidance to support this goal.

In addition to the issues related to deliveries that prompt hospitals to contact CENABAST, another frequent reason for communication is the handling of exchange letters (CENABAST, 2024). These documents must accompany products dispatched with a shorter shelf life than stipulated in the Intermediation bases (*Exempt Resolution No. 087/2022*), allowing hospitals to request replacements or issue credit notes if the product expires before use. Although the bases require the exchange letter to be provided with the shipment, interviews with hospitals revealed several issues.

Firstly, the letters are often not delivered with the products, requiring hospitals to address the issue through CENABAST. Secondly, suppliers usually delay retrieving the replaced products. A similar problem occurs with products suppliers must remove from the market due to health alerts. A Public Health Institute (ISP)²⁶ resolution establishes the responsibility and timelines for executing such recalls.

²⁴ Evidence supporting this statement can be found in CENABAST's *Ordinance No. 1844/2018*, which reports on the "Traceability and Visibility System" project to the Senate's Joint Special Budget Committee, and also in the Central's User Manual. The manual specifies that establishments report the quantities received, and suppliers report deliveries, through the CENABAST website.

²⁵ This may be less than or equal to the quantity depending on the product availability reported by the supplier.

²⁶ *Exempt Resolution 3853/2020*.

In both situations—product exchange or health-related recalls—hospitals report lacking mechanisms to enforce timely retrieval by suppliers. As a result, the hospitals must store these items during the supplier's delay, using their limited storage space and allocating staff time to repeatedly follow up on these issues. The Intermediary bases do not establish deadlines or financial penalties for these situations. The only exception is for market recalls, classified as a serious breach, leading to administrative sanctions such as early contract termination.

Recommendation 2.11 proposes introducing deadlines for product exchanges and explicitly referencing the ISP resolution regarding health alerts to address these issues. Financial penalties for non-compliance could also create more explicit guidelines and incentivize suppliers to expedite product retrieval.

The Health Registry is crucial for ensuring a minimum quality standard in public procurement and enabling continuous monitoring of the quality and safety of purchased products, regardless of the procurement channel. Unlike pharmaceuticals, medical devices in Chile show a significant lag in registration. Out of an estimated 57,000 devices, only 10 are registered, representing a coverage rate of just 0.018% compared to 100% for pharmaceuticals. This low coverage contrasts sharply with the substantial share medical devices represent in clinical supply spending—60% of the total, equivalent to USD 900 million in 2023. In comparison, countries like the United States and the European Union register between 17,000 and 20,000 devices.

Given this disparity, advancing the regulation of medical devices is critical. To achieve this, the ISP must be granted the authority to conduct an efficient process for registering and monitoring medical devices. Considering the gap in the number of medical devices requiring registration, the *Reliance* and *Recognition*²⁷ principles promoted by the World Health Organization (2017) should explicitly form part of the ISP's mandate. These principles would enable a more efficient incorporation of devices into the registry.

Additionally, since monitoring represents the ISP's most resource-intensive task, it should be supported through third-party audits, as seen in other countries.

Since March 2015, the *Medicines Law 2 (LF2)* project has been under discussion in Congress. Initially, it aimed to amend the Health Code to regulate pharmaceuticals.²⁸ In 2016, a parliamentary motion was introduced to amend Article 111 of the Health Code, requiring medical devices to be registered for commercialization. This motion was incorporated into the LF2 project in 2018. However, nearly a decade later, the project remains under

²⁷ Practices that allow the ISP to adopt, if desired, the evaluation or direct marketing authorization from other trusted regulatory bodies, such as the Food and Drug Administration (FDA) or the European Medicines Agency (EMA).

²⁸ In particular, it sought to amend the code to regulate generic bioequivalent medications and prevent vertical integration between laboratories and pharmacies.

discussion. Interviews in this study suggest that the delay is primarily due to debates surrounding pharmaceuticals rather than medical devices. Interviews with public and private stakeholders reveal that the sections of the project related to medical devices enjoy broad consensus, albeit with minor differences. International evidence also shows that the regulation of pharmaceuticals and medical devices is typically handled separately, as seen in the United States, the European Union, and Brazil.

Recommendation 2.12 suggests separating the medical device-related articles from the LF2 project to facilitate progress in registering medical devices. These include Article 111, Articles 111 BIS through 111 DECIES, Article 129P, and the transitional implementation article, to be submitted as a new legislative proposal for discussion.

Alongside this, **Recommendations 2.13 to 2.17** propose amendments to the LF2 project to:

- Explicitly grant the ISP the authority to apply internationally aligned strategies for regulating and certifying devices (Reliance and Recognition).
- Facilitate ISP monitoring with support from third-party audits.
- Create a mechanism to regulate critical medical device representatives with standards similar to those in the proposal.
- Extend the implementation timeline to at least three years, following practices in the European Union and WHO recommendations.

Lastly, **Recommendation 2.18** emphasizes prioritizing the registration of key medical devices, as MINSAL already has the authority to undertake this task.

Traceability and Logistics Operations

The third and final topic examines supply chain traceability processes and in-hospital supply management. To enhance safety, healthcare effectiveness, and spending efficiency, other countries have developed traceability systems that allow tracking of pharmaceuticals and/or medical devices throughout the supply chain.²⁹ Evidence suggests that implementing pharmaceutical traceability systems can take around five years and require an initial investment of approximately USD 200 million.

Regarding in-hospital management, there is a pressing need to improve stock management, providing more detailed insights into the availability of pharmaceuticals and devices within central and peripheral storage facilities. Implementing robust traceability systems is essential to ensure the secure distribution, storage, and dispensing of pharmaceuticals and medical devices to patients.

²⁹ See, for example, Mackey and Nayyar (2017).

The recommendations emphasize automating and digitizing inventory management processes, adopting global product identification standards, and implementing a traceability system for medications and medical devices. These measures aim to maintain products in optimal conditions, minimize losses due to expiration or deterioration, keep accurate inventory records, reduce fraud and theft, and provide actionable data on future pharmaceutical needs.³⁰

Chile lacks a system to trace a medication or medical device from its importer or manufacturer to its hospital dispensing. While some such systems may exist at a limited scale in private healthcare facilities,³¹ public hospitals exhibit significant variability in their ability to record the inflow and outflow of pharmaceuticals and medical devices from their storage facilities and pharmacies.

Evidence shows that diverse systems are used across hospitals and within units of the same establishment, ranging from commercial software and in-house developments to spreadsheets and manual records. Many of these systems are outdated or unreliable, as reported by healthcare staff. Additionally, unregulated storage of pharmaceuticals and devices in peripheral warehouses within healthcare facilities is common. These warehouses may hold more than 40% of a hospital's valued inventory, with up to 60% of the stock potentially not inventoried.³² Compounding these issues is the staff's low adherence to the proper use of available systems³³ and frequent turnover in hospital leadership positions under the *High Public Management* framework. This turnover disrupts the implementation of medium—and long-term strategies for improving inventory management.³⁴

These factors undermine the integrity of inventory records, increasing product loss and hindering feedback to procurement units for defining purchase requirements. According to reports from the *Comptroller General of the Republic (CGR)*, the annual loss of medications in public health services during 2017 and 2018 may have represented 1.28% of procurement

³⁰ See Management Sciences for Health (2012)

³¹ For example, *Technical Standard No. 226 of 2022* from MINSAL introduced, at the facility level, the obligation to implement a data recording system to enable the traceability of medical devices upon their receipt by institutional providers. This standard stipulated that the records would operate in a decentralized manner, meaning they would be maintained locally by each facility. The records could be kept either physically or electronically, with each facility responsible for developing procedures that comply with the standard.

³² According to documents shared as part of the study by high-complexity hospitals.

³³ See, for example, *Final Report No. 137/2019* by the CGR.

³⁴ Around 60% of departures from hospital leadership positions (associated with ADP) in a year are related to individuals who had been in the

value in 2022.³⁵ By comparison, hospitals reported an average loss of 0.66% in their *Management Commitments (COMGES)* for the same year.

Additionally, the lack of data on actual consumption and inventory within facilities prevents proper planning for material needs. This issue is exacerbated by the inability to link the consumption of pharmaceuticals and medical devices to specific patients, making it difficult to analyze treatment costs and evaluate the effectiveness of innovative therapies.

Another challenge in tracking pharmaceuticals or medical devices throughout the supply chain is the lack of standardized identification systems and necessary support to link them to specific products. Currently, without a traceability system, *Technical Standard No. 147* issued by MINSAL, which establishes good practices for storing and distributing pharmaceuticals, does not specify supports or standards for product identification.

For example, CENABAST and the Public Market platform use their product codes.³⁶ However, holders of health registrations are generally aligned with international standards for supply traceability, widely utilizing barcodes and Datamatrix³⁷ as identification tools and applying GS1 as the standard for product identification.^{38, 39}

Traceability improves management and brings significant benefits to safety and the control of illegal trafficking of pharmaceuticals and medical devices. By enabling tracking and monitoring throughout the supply chain, traceability systems can identify diversion points for illegal trafficking and facilitate faster and more effective market withdrawals (WHO, 2021; McKinsey, 2012). This aspect has gained importance recently due to a global increase in incidents involving counterfeit or unauthorized medicines.⁴⁰

While evidence suggests this is still an emerging issue in Chile, the trend raises concern. For instance, ketamine seizures by the Chilean Investigative Police reached record levels in 2024, and data from the Metropolitan Region showed alarming increases, with pharmaceutical product seizures rising by 1,000% between 2021 and 2022.⁴¹ Additionally, thefts from pharmaceutical transport trucks surged by 400% during the same period, and significant thefts of medicines have been reported in hospitals and clinics.⁴² Market withdrawals of pharmaceuticals and medical devices also threaten patient safety when products are not

³⁵ From the CGR: *Final Report No. 244/2020; COMGES 2022 Valuation*. The biennial loss was divided by two and updated to reflect the accumulated CPI between January 2017 and January 2022, according to the CPI Calculator. The estimated annual loss, adjusted for CPI, was approximately 2.648 billion pesos.

³⁶ CENABAST uses the identifier ZGEN, while the Public Market uses the UN code.

³⁷ A two-dimensional symbol arranged in a matrix of square modules that encodes a large amount of information in a small space and can be read by two-dimensional image scanners or vision systems.

³⁸ GS1 is a non-profit organization that proposes a common language for the unique identification of products through standardized coding. They develop serializations based on standards that enable the unique identification of products and even individuals and facilities in the healthcare sector.

³⁹ ISP Presentation: Implementation of a Drug Traceability System (GAR5 2021).

⁴⁰ See statistics of the Pharmaceutical Security Institute o OMS (2023

⁴¹ See Cooperativa, 2024; ISP, 2023.

⁴² See r ISP, 2023 and CIPER, 2023.

adequately removed. Data indicates that health alerts are increasing globally, including in Chile, and that, on average, 5% to 10% of products are not withdrawn despite exhaustive and costly efforts by hospital staff and suppliers (McKinsey, 2012).⁴³

International experience and guidance from organizations such as the World Health Organization (WHO) underscore the need for a consistent policy to improve the traceability of medical supplies. **Recommendation 3.1** suggests creating a task force to design and implement a national traceability policy for pharmaceuticals and medical devices. This effort, coordinated by the Ministries of the Interior, Finance, and Health, should consider healthcare, budgetary, and security aspects.

Complementing the task force's work, **Recommendation 3.2** proposes a study to identify and quantify gaps within the industry and among healthcare providers. Similarly, **Recommendation 3.3** calls for a specific diagnosis of the public healthcare network's inventory management shortcomings to facilitate the transition to a national traceability system.

The chapter concludes by addressing the conditions under which clinical supplies are managed in public hospitals, proposing an alternative to improve the quality of this process. It highlights issues stemming from inadequate storage conditions and the use of unauthorized spaces, emphasizing the need to correct these practices to ensure more efficient and secure supply management. These issues were identified during hospital visits and through reviews of reports by the *Comptroller General of the Republic (CGR)*.⁴⁴

The current situation results from a combination of factors, including insufficient investment in and maintenance of hospital infrastructure, long restocking times associated with certain procurement channels, uncertainty regarding delivery reliability, and the lack of systems to monitor actual inventory levels and their locations within hospitals. This impedes accurate purchase planning and makes safeguarding products awaiting exchange, quarantine, or market withdrawal difficult.

Restocking times, primarily through CENABAST's Intermediation channel, involve large delivery volumes,⁴⁵ often based on monthly shipments. Concerns about the completeness and timeliness of orders have led facilities to request additional quantities to mitigate risks of future delivery failures—products immobilized while awaiting exchange, health-related withdrawal, or quarantine further strain already limited storage capacity.

⁴³ See Figure 2.2 in the Annex.

⁴⁴ See Tables 3.1; 3.2 and 3.3 in the Annex

⁴⁵ Particularly pallets of IV fluids.

Recognizing the challenges of managing acquired volumes under optimal conditions, some facilities have begun outsourcing storage and associated logistics services.⁴⁶ If implemented at a network level, this solution could align with models used in the United Kingdom and Peru, which have demonstrated positive outcomes, such as reduced waste, overstocking, and improved inventory management through better hospital equipment. In these models, support services like receiving, storage, and last-mile distribution are outsourced to logistics operators serving a network of facilities. This enables hospitals to maintain smaller inventories on-site, following a just-in-time approach with smaller, more frequent orders handled by the contracted operator. This model also facilitates introducing standardized technology across the network for inventory management, supporting the implementation of internal traceability strategies.

The proposal also addresses concerns raised by Intermediary providers regarding distribution efficiency. The *CENABAST 2023 Supplier Meeting* document highlights that the primary procurement modality under CENABAST Intermediation does not guarantee minimum purchase volumes, and suppliers' distribution points may change monthly. The evidence suggests that the distribution points could reach approximately 176 facilities nationwide. This variability is problematic for suppliers, as it introduces risks beyond their control, underscoring the importance of consolidating orders to improve distribution efficiency.

The findings reveal significant gaps in supply management within hospitals, largely attributable to the abovementioned factors. **Recommendation 3.4** proposes exploring a public-private partnership model to improve hospital inventory management. This would include services such as last-mile logistics, consolidated dispatches, storage, and receiving for the hospital network, along with equipment for inventory management and facility traceability. Evidence suggests this model could also be extended to secondary and primary care facilities.

This study provides recommendations to optimize hospital spending efficiency by improving processes related to the procurement, inventory management, and distribution of medical and pharmaceutical supplies. The proposals aim to create efficiencies in processes and spending—enabling the purchase of more supplies within the same budget—and ensure better quality patient care. Implementing these recommendations collectively would contribute to a more efficient and transparent use of resources, benefiting both system users and institutional management.

⁴⁶ Notably, the rented storage spaces are equivalent to between 1 and 3 times the average total storage area allocated in the designs of new hospitals. The average was calculated based on data from 10 hospitals included in the 2nd PPP program.

Considerations

Finally, it is important to highlight certain aspects related to the procurement of goods and services by hospitals that were not addressed in this study—not due to their low relevance, but quite the opposite. These are issues of significant complexity that require dedicated efforts. One such aspect concerns procuring services from medical societies or individual medical professionals.

While these services are part of hospitals' routine procurement activities, their nature presents additional challenges beyond management. Many of these services are provided by the hospital's staff. It is worth noting that, as observed in this study, implementing the new *Procurement Law* encourages hospitals to increasingly rely on the Direct Contracting channel for procuring these services. This approach is often less efficient since prices associated with direct contracting tend to be higher than those of more competitive channels like public Bidding.

Another issue addressed tangentially through the recommendations on service packaging relates to hospital debt. This problem extends beyond hospital procurement, as the structural causes of the misalignment between hospital revenues and expenditures are not limited to the processes of purchasing and managing supplies. However, these issues manifest in acquisitions through delayed payments or an inability to purchase due to a lack of resources. One such structural factor is related to the cost of hospital activities, which, as evidenced in the study, is highly heterogeneous among hospitals.

Reducing this heterogeneity to improve the financing system is challenging and requires institutional efforts beyond better procurement and inventory management. The Ministry of Finance and the Ministry of Health are the key institutions tasked with leading efforts in this area.

Lastly, another topic mentioned but not explored in depth is related to *Shared Risk Agreements*. While evidence suggests that certain types of agreements, such as those associated with financial risk, are already utilized to some extent, more innovative agreements aim to define the obligations and rights of the involved parties through treatment outcomes and follow-ups.

Interviews conducted with various representatives from the public and private sectors revealed that, like the previously mentioned cases, this issue is also complex. It involves the hospital network, which must be capable of tracking consumption down to the patient level over time (to analyze treatment effectiveness), and institutional actors, including the Ministry of Finance, the Ministry of Health, and the public insurer FONASA.