RESEARCH PAPER

Strengthening Indonesia's Pharmaceutical Supply Chain Resilience: Reducing Import Dependence on Active Pharmaceutical Ingredients for National Health Security

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Abstract
Indonesia's dependence on imported active pharmaceutical ingredients (APIs) creates systemic risks to national health security, particularly during health crises and global supply chain disruptions. Although the country has a large domestic pharmaceutical manufacturing base, the upstream segment of the pharmaceutical value chain remains exposed to external shocks because many essential medicines depend on imported raw materials. This article analyzes API import dependence as a structural vulnerability in Indonesia's health security system and develops a policy framework for strengthening pharmaceutical supply chain resilience. Using qualitative policy analysis, the study examines official policy documents, institutional publications, and academic literature on pharmaceutical resilience, medicine security, systemic risk, and health system resilience. The article proposes the Pharmaceutical Supply Resilience for Health Security (PSR-HS) Framework, consisting of domestic API capacity, supplier diversification, strategic stockpiling, regulatory acceleration, and research–industry integration. The framework argues that reducing API dependence requires more than import substitution; it requires integrated industrial policy, regulatory reform, crisis preparedness, supply chain risk governance, and innovation ecosystem development. The article contributes to pharmaceutical policy and health security studies by linking API dependence with systemic risk and national resilience.

Keywords: active pharmaceutical ingredients; pharmaceutical supply chain resilience; import dependence; national health security; medicine security; Indonesia

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1. Introduction

The availability of medicines is a fundamental component of health system performance and national health security. Medicines are not merely commercial products exchanged through ordinary markets; they are critical health security assets that sustain clinical services, disease control, emergency response, and population welfare. When essential medicines become unavailable, delayed, unaffordable, or unreliable, the impact can move beyond the pharmaceutical sector and generate cascading pressure across hospitals, primary health care facilities, public procurement systems, insurance mechanisms, and household health expenditure. This is why pharmaceutical supply chain resilience must be understood as a strategic policy concern rather than a narrow industrial issue. (OECD, 2024; World Health Organization, 2020, 2024)

Indonesia's pharmaceutical sector presents an important paradox. On the one hand, the country has a significant domestic pharmaceutical manufacturing capacity and has long been able to produce a large share of finished medicine requirements for the domestic market. On the other hand, the upstream inputs used to manufacture many finished medicines remain heavily dependent on imported active pharmaceutical ingredients and other pharmaceutical raw materials. The Ministry of Health has noted that while domestic industry can meet most finished medicine needs, production has historically relied on imported raw materials, creating a gap between downstream production capability and upstream raw material independence. (Kementerian Kesehatan Republik Indonesia, 2012a, 2012b; Badan Kebijakan Pembangunan Kesehatan, 2022)

This gap is strategically important because APIs are the pharmacologically active components that determine the therapeutic function of a medicine. Without stable access to APIs, domestic manufacturers cannot reliably produce essential medicines, even if they possess factories, packaging capacity, distribution networks, and domestic market access. API dependence therefore represents a hidden vulnerability in the pharmaceutical system: the visible downstream system may appear strong, while the upstream foundation remains exposed to international supply volatility, logistics disruptions, export restrictions, geopolitical shocks, quality failures, and currency movements. (Christopher & Peck, 2004; OECD, 2024; Ponomarov & Holcomb, 2009)

The COVID-19 pandemic exposed how health systems can be disrupted not only by disease transmission but also by shortages of medicines, medical devices, personal protective equipment, diagnostic supplies, and raw materials. WHO emphasized that health systems overwhelmed by outbreaks may struggle to maintain essential services, leading to indirect morbidity and mortality from treatable conditions. For countries with high import dependence, disruption in medical supply chains can reduce the ability to maintain

essential health services while responding to crisis demand. (World Health Organization, 2020; Ivanov, 2020; OECD, 2024)

For Indonesia, the pandemic strengthened the policy logic of pharmaceutical independence and domestic production of critical health commodities. The Ministry of Health has framed domestic pharmaceutical raw material production as part of health resilience and has promoted policies such as change source facilitation, research and development support, import trade governance, market assurance, and incentives for industries that shift from imported to domestic raw materials. These policy directions indicate that API dependence is now recognized as part of the broader agenda of health system transformation and national resilience. (Kementerian Kesehatan Republik Indonesia, 2023, 2025; Badan Kebijakan Pembangunan Kesehatan, 2022)

Nevertheless, policy recognition alone does not automatically produce resilience. Pharmaceutical supply chain resilience requires the ability to anticipate, absorb, adapt to, and recover from disruptions affecting raw materials, manufacturing, logistics, quality assurance, distribution, and procurement. Resilience is therefore not limited to local production; it also requires diversified sourcing, strategic reserves, transparent risk mapping, regulatory flexibility, supplier qualification, quality assurance, and long-term coordination between government, industry, research institutions, and regulators. (Christopher & Peck, 2004; Ponomarov & Holcomb, 2009; World Health Organization, 2024)

The central argument of this article is that Indonesia's dependence on imported APIs is not merely an industrial limitation but a systemic vulnerability that can undermine national health security during health crises and global supply chain disruptions. This vulnerability becomes systemic because API shortages can affect medicine availability, hospital readiness, public procurement, price stability, clinical continuity, emergency preparedness, and public trust in the health system. A disruption in upstream pharmaceutical inputs can therefore generate downstream consequences across multiple health system functions. (OECD, 2024; World Health Organization, 2007, 2020)

Existing studies on supply chain resilience have emphasized disruption preparedness, supplier diversification, flexibility, collaboration, visibility, redundancy, and recovery capability. However, pharmaceutical supply chains differ from ordinary supply chains because medicines are regulated products with strict requirements for quality, safety, efficacy, bioequivalence, registration, procurement, and pharmacovigilance. Supplier change cannot be conducted as casually as in many other industries because pharmaceutical products require regulatory approval and quality assurance. This makes pharmaceutical resilience both a supply chain challenge and a regulatory governance challenge. (Christopher & Peck, 2004; Ponomarov & Holcomb, 2009; Kementerian Kesehatan Republik Indonesia, 2023)

This article seeks to answer the following research question: How can Indonesia strengthen pharmaceutical supply chain resilience by reducing import dependence on active pharmaceutical ingredients in order to support national health security? This question is addressed through a qualitative policy analysis that combines document analysis, thematic policy interpretation, supply chain risk mapping, and conceptual framework development. The article proposes the Pharmaceutical Supply Resilience for Health Security (PSR-HS) Framework as an integrative policy model. (Bowen, 2009; Bardach & Patashnik, 2020; Braun & Clarke, 2006)

The contribution of this article is threefold. First, it reframes API import dependence as a national health security problem rather than a narrow industrial problem. Second, it develops an integrated framework that connects domestic API capacity, supplier diversification, strategic stockpiling, regulatory acceleration, and research–industry integration. Third, it provides policy implications for strengthening Indonesia's medicine security and crisis preparedness in an era of global supply chain uncertainty. (World Health Organization, 2007; OECD, 2024; Kementerian Kesehatan Republik Indonesia, 2025)

2. Literature Review

Active pharmaceutical ingredients are central to the pharmaceutical value chain because they constitute the biologically or chemically active substance responsible for a medicine's therapeutic effect. Finished pharmaceutical products depend on stable access to APIs, excipients, packaging materials, quality testing systems, production facilities, and distribution networks. In policy terms, API availability determines whether domestic manufacturing capacity can be translated into real medicine security. A country may have strong finished-product manufacturing capacity, but if it lacks reliable access to APIs, the medicine supply system remains structurally exposed. (OECD, 2024; Kementerian Kesehatan Republik Indonesia, 2012a; Badan Kebijakan Pembangunan Kesehatan, 2022)

API dependence is a global concern because pharmaceutical production has become internationally fragmented. Many medicines rely on raw materials, intermediates, APIs, formulation sites, packaging sites, and distribution channels located across different countries. This fragmentation may increase efficiency under normal market conditions, but it can also increase vulnerability when disruptions affect specific countries, transport routes, quality systems, or export policies. Globalized pharmaceutical production therefore creates a trade-off between cost efficiency and security of supply. (OECD, 2024; Christopher & Peck, 2004; Ivanov, 2020)

The OECD has argued that medical supply chains are foundational to resilient health systems and that shortages of medicines can have wide implications, including delayed treatment, increased costs, pressure on health care workers, and loss of productivity. The OECD also highlights that shortages existed before COVID-19 but became more visible during the pandemic because demand surges, manufacturing constraints, and logistics bottlenecks interacted simultaneously. This shows that medicine security cannot be separated from supply chain governance. (OECD, 2024)

Pharmaceutical supply chains are vulnerable not only because of international fragmentation but also because of concentration risk. When APIs or critical manufacturing steps are concentrated in a small number of sites or countries, a localized disruption can become a global supply problem. Concentration may be economically rational in stable conditions, but it weakens resilience when the system faces pandemics, natural disasters, geopolitical tensions, quality failures, or export restrictions. Resilience therefore requires attention to both efficiency and redundancy. (OECD, 2024; Christopher & Peck, 2004; Ponomarov & Holcomb, 2009)

In Indonesia, the policy problem is sharper because the country has a large domestic market and domestic finished medicine production capacity but remains dependent on imported pharmaceutical raw materials. BKPK Kemenkes has stated that more than 90 percent of drug raw materials are imported and that reducing dependence on imported raw materials is part of the Ministry of Health's strategic policy concern. This indicates that API dependence is a recognized structural problem in Indonesia's pharmaceutical sector. (Badan Kebijakan Pembangunan Kesehatan, 2022)

Historical Ministry of Health communications also show that Indonesia's domestic pharmaceutical industry can meet a large share of finished medicine demand, but the raw material base is highly dependent on imports. This pattern creates what can be called downstream strength with upstream fragility. The country may appear self-sufficient at the level of finished product production, but the ability to sustain that production depends on the continuity of imported APIs and other raw materials. (Kementerian Kesehatan Republik Indonesia, 2012a, 2012b)

Supply chain resilience theory offers useful concepts for understanding this condition. Christopher and Peck describe resilient supply chains as systems capable of reducing vulnerability and improving the ability to respond to disruption. Ponomarov and Holcomb define supply chain resilience as adaptive capability to prepare for unexpected events, respond to disruption, and recover by maintaining continuity of operations. These concepts are relevant to pharmaceutical policy because medicine supply failure can directly affect patient safety and health system continuity. (Christopher & Peck, 2004; Ponomarov & Holcomb, 2009)

Resilience, however, is not the same as self-sufficiency. No country can realistically produce every pharmaceutical raw material domestically, and the Ministry of Health has acknowledged that no country can produce all its own medicine raw materials. A resilience approach therefore does not demand total autarky. Instead, it asks which APIs are critical, which dependencies are risky, which suppliers are concentrated, which domestic capacities are feasible, and which emergency mechanisms can protect essential medicine availability. (Kementerian Kesehatan Republik Indonesia, 2012a; OECD, 2024)

Medicine security refers to the reliable availability of safe, effective, quality-assured, and affordable medicines needed by the population. In health system terms, medicine security is connected to universal health coverage, essential health services, public procurement, hospital readiness, and emergency response. When API supply is disrupted, medicine security may be weakened even when domestic demand forecasting and distribution channels are functioning. (World Health Organization, 2020, 2024; OECD, 2024)

Health security provides the broader strategic lens for this article. WHO defines global public health security as proactive and reactive activities required to minimize vulnerability to acute public health events that endanger population health across geographical regions and international boundaries. Although this definition is often applied to infectious disease threats, it is also relevant to pharmaceutical supply vulnerability because medicine shortages can amplify the impact of public health emergencies. (World Health Organization, 2007)

WHO's work on health system resilience emphasizes the capacity of health systems to prevent, prepare for, detect, adapt to, respond to, and recover from public health threats while maintaining essential and routine health services. Pharmaceutical supply is a critical enabling function within this resilience agenda. A health system cannot maintain essential services if essential medicines and raw materials are unavailable or unstable. (World Health Organization, 2024; World Health Organization, 2020)

During COVID-19, WHO warned that overwhelmed health systems could experience indirect increases in mortality from treatable conditions if essential services are disrupted. Medicine shortages can contribute to such indirect harm by interrupting chronic disease treatment, emergency care, infectious disease management, maternal health services, and noncommunicable disease programs. This connection shows why pharmaceutical supply resilience should be placed within health security planning. (World Health Organization, 2020)

The literature on pharmaceutical shortages shows that shortages can emerge from multiple causes, including manufacturing quality problems, economic

incentives, low prices for generic medicines, regulatory issues, logistics disruptions, and supplier concentration. The OECD notes that shortages were already common before COVID-19 and that the pandemic intensified the problem by exposing bottlenecks in global medical product supply chains. For Indonesia, this means API import dependence should be analyzed alongside quality, price, logistics, and regulatory factors. (OECD, 2024)

Regulatory governance is particularly important in the pharmaceutical sector because changing an API supplier requires scientific, quality, and regulatory evaluation. Indonesia's change source policy is therefore strategically significant because it facilitates the shift from imported raw materials to domestically produced raw materials. However, change source policies must be supported by quality assurance, market confidence, procurement incentives, and industry readiness. Otherwise, the availability of domestic APIs may not automatically lead to widespread adoption by finished medicine manufacturers. (Kementerian Kesehatan Republik Indonesia, 2023, 2025)

Strategic stockpiling is another important concept in pharmaceutical resilience. Stockpiling can protect medicine availability during short-term shocks, but it must be carefully designed because APIs and medicines have expiry dates, storage requirements, quality risks, and inventory rotation needs. Stockpiling should therefore be linked to essential medicine lists, risk classification, procurement planning, and emergency distribution mechanisms. It should complement rather than replace domestic production and diversified sourcing. (OECD, 2024; World Health Organization, 2020)

Supplier diversification is also central to resilience. Relying on a single country, supplier, or logistics route may reduce procurement complexity under normal conditions but increases exposure during crisis. Diversification can include dual sourcing, regional sourcing, long-term supplier qualification, framework agreements, and strategic partnerships. However, diversification also involves trade-offs because alternative suppliers may have different prices, quality systems, regulatory documents, and production reliability. (Christopher & Peck, 2004; Ponomarov & Holcomb, 2009; OECD, 2024)

Domestic API capacity represents the industrial dimension of pharmaceutical resilience. Developing API production requires investment, technology, skilled human resources, environmental management, quality systems, economies of scale, and stable market demand. Without market assurance, domestic producers may struggle to compete with imported APIs that are cheaper because of global scale, established supply chains, and integrated chemical industries. Therefore, industrial policy and health policy must be coordinated. (Badan Kebijakan Pembangunan Kesehatan, 2022; Kementerian Kesehatan Republik Indonesia, 2025)

Research–industry integration is required because API development is technologically demanding and cannot rely solely on procurement policy. Universities, research institutions, pharmaceutical state-owned enterprises, private industries, regulators, and health system planners need structured collaboration to move from laboratory research to pilot production, regulatory approval, industrial scale-up, and market adoption. This integration is especially important for priority molecules that are clinically essential and highly vulnerable to import disruption. (Kementerian Kesehatan Republik Indonesia, 2012a, 2025; Badan Kebijakan Pembangunan Kesehatan, 2022)

The literature therefore suggests that API dependence should be understood through a multi-dimensional framework. It is simultaneously a supply chain issue, industrial policy issue, regulatory issue, health security issue, and crisis preparedness issue. A narrow import-substitution approach is insufficient because it may focus on replacing imported inputs without addressing supplier risk, quality confidence, stockpiling, regulatory speed, and innovation capacity. (OECD, 2024; World Health Organization, 2024; Kementerian Kesehatan Republik Indonesia, 2025)

Based on this review, the article identifies a research gap in the Indonesian context. Existing discussions often emphasize pharmaceutical independence, finished medicine production, or domestic industry development, but less attention has been given to API import dependence as a systemic risk to national health security through the lens of pharmaceutical supply chain resilience. The PSR-HS Framework is proposed to address this conceptual and policy gap. (Badan Kebijakan Pembangunan Kesehatan, 2022; OECD, 2024; World Health Organization, 2007)

3. Methodology

This study employs a qualitative policy analysis approach to examine Indonesia's dependence on imported active pharmaceutical ingredients and its implications for national health security. Qualitative policy analysis is appropriate because the study does not aim to measure pharmaceutical dependence through statistical modeling, but to interpret policy documents, institutional responses, supply chain vulnerabilities, and strategic policy options related to pharmaceutical resilience. (Bardach & Patashnik, 2020; Bowen, 2009)

The research is designed as a conceptual-policy study. It combines document analysis, thematic policy interpretation, supply chain risk mapping, and framework development. This design is suitable for a study that seeks to generate a policy framework rather than test a causal hypothesis through quantitative methods. The main analytical output is the PSR-HS Framework, which connects domestic API capacity, supplier diversification, strategic stockpiling, regulatory acceleration, and research–industry integration. (Bowen, 2009; Braun & Clarke, 2006; Creswell & Creswell, 2018)

The study uses secondary data from official documents, institutional publications, international policy reports, and academic literature. Indonesian sources include Ministry of Health publications, BKPK policy communications, and documents related to pharmaceutical independence, raw material production, change source policy, and health resilience. International sources include WHO documents on health security and health system resilience, OECD reports on medical supply chains, and academic literature on supply chain resilience and pharmaceutical shortages. (Badan Kebijakan Pembangunan Kesehatan, 2022; Kementerian Kesehatan Republik Indonesia, 2023, 2025; OECD, 2024; World Health Organization, 2007, 2024)

Documents were selected based on five criteria. First, they had to be relevant to active pharmaceutical ingredients, pharmaceutical raw materials, medicine availability, supply chain disruption, pharmaceutical independence, or national health security. Second, they had to come from credible sources such as government institutions, international organizations, peer-reviewed journals, or reputable policy institutions. Third, they had to contain substantive information about policy direction, supply chain vulnerability, pharmaceutical resilience, or health system risk. Fourth, they had to contribute to the development of the PSR-HS Framework. Fifth, priority was given to post-COVID-19 sources when available because the pandemic exposed major vulnerabilities in global medical supply chains. (Bowen, 2009; Creswell & Creswell, 2018)

Data collection was conducted through systematic document gathering. The first step was identifying the main concepts of the study: active pharmaceutical ingredients, import dependence, pharmaceutical supply chain resilience, medicine security, health security, systemic risk, and pharmaceutical independence. The second step was collecting relevant documents from official government sources, international organizations, academic databases, and policy reports. The third step was screening the documents based on relevance, credibility, recency, and conceptual contribution. (Bardach & Patashnik, 2020; Bowen, 2009)

The selected documents were organized into six thematic clusters: API import dependence, pharmaceutical supply chain vulnerability, medicine availability and medicine security, health crisis and supply chain disruption, domestic pharmaceutical production and industrial policy, and pharmaceutical resilience for national health security. These clusters were then arranged into a document matrix containing source identity, year, institution or author, main issue, key argument, and relevance to the PSR-HS Framework. (Braun & Clarke, 2006; Bowen, 2009)

The data were analyzed using thematic policy analysis. The first stage was policy mapping to identify Indonesia's current policy direction on pharmaceutical independence, domestic API production, change source policy, local production incentives, medicine availability, and health security. This stage helped identify the institutional and policy context within which API dependence is being addressed. (Bardach & Patashnik, 2020; Kementerian Kesehatan Republik Indonesia, 2023, 2025)

The second stage was supply chain risk mapping. This stage identified vulnerabilities caused by import dependence, supplier concentration, logistics disruption, export restrictions, currency volatility, quality concerns, and limited domestic API production. Risk mapping was used to connect upstream supply vulnerabilities with downstream consequences for medicine availability, public procurement, and health service continuity. (Christopher & Peck, 2004; OECD, 2024; Ponomarov & Holcomb, 2009)

The third stage was thematic coding. The data were classified into five analytical themes: domestic API capacity, supplier diversification, strategic stockpiling, regulatory acceleration, and research–industry integration. These themes were selected because they repeatedly appeared in the literature and policy documents as core elements of pharmaceutical resilience. (Braun & Clarke, 2006; Kementerian Kesehatan Republik Indonesia, 2025; OECD, 2024)

The fourth stage was gap analysis. This stage identified weaknesses in Indonesia's pharmaceutical supply chain resilience, particularly the gap between downstream finished medicine manufacturing capacity and upstream API independence. The analysis also examined the gap between policy recognition and implementation capability, including market adoption, regulatory speed, supplier confidence, and research-commercialization linkages. (Badan Kebijakan Pembangunan Kesehatan, 2022; Kementerian Kesehatan Republik Indonesia, 2023)

The fifth stage was framework development. The PSR-HS Framework was constructed by synthesizing findings from document analysis, literature review, and supply chain risk mapping. The framework is not presented as an empirical measurement model but as a conceptual policy model that can guide future empirical research, stakeholder consultation, and policy design. (Bardach & Patashnik, 2020; Bowen, 2009; Creswell & Creswell, 2018)

The study applies source triangulation and conceptual triangulation to strengthen trustworthiness. Source triangulation compares information from government documents, international organizations, academic literature, and policy reports. Conceptual triangulation compares concepts from pharmaceutical supply chain resilience, health security, medicine security, systemic risk, and industrial policy. Internal consistency checking was also applied to ensure that research questions, methodology, findings, framework, and policy recommendations are logically connected. (Creswell & Creswell, 2018; Patton, 2015)

The study uses only publicly available documents and does not involve human subjects, personal health data, confidential business information, classified state documents, or proprietary supply contracts. Therefore, the study does not require human subject ethical clearance. The analysis avoids speculative claims and focuses on policy-level interpretation based on available public evidence. (Bowen, 2009; Creswell & Creswell, 2018)

The study has limitations. It relies on secondary data and may not capture internal policy deliberations, confidential procurement contracts, proprietary industry data, or actual real-time inventory levels. It also does not conduct quantitative modeling of API import flows, medicine shortage probability, or supply chain network structure. Future research can validate the PSR-HS Framework through expert interviews, stakeholder workshops, comparative case studies, or quantitative risk modeling. (Creswell & Creswell, 2018; Patton, 2015)

4. Results

The first finding is that Indonesia's pharmaceutical resilience problem is characterized by downstream strength but upstream dependence. Domestic pharmaceutical manufacturers are important actors in meeting medicine needs, yet the production of many finished medicines remains dependent on imported APIs and raw materials. This creates a structural vulnerability because production continuity depends on external suppliers, international logistics, and foreign regulatory and industrial conditions. (Kementerian Kesehatan Republik Indonesia, 2012a, 2012b; Badan Kebijakan Pembangunan Kesehatan, 2022)

This upstream dependence is not a marginal issue. BKPK Kemenkes states that more than 90 percent of drug raw materials are imported and that raw materials account for a significant portion of the national pharmaceutical business value. This indicates that API dependence is embedded in the economic structure of the pharmaceutical sector. It also means that medicine security is influenced by factors outside the direct control of domestic health authorities and manufacturers. (Badan Kebijakan Pembangunan Kesehatan, 2022)

The second finding is that API dependence creates systemic risk because a disruption in upstream supply can affect multiple downstream health system functions. If APIs become delayed, scarce, expensive, or unavailable, manufacturers may face production delays, procurement systems may face shortage risks, hospitals may experience medicine availability problems, and patients may face treatment interruption or higher costs. This illustrates the cascading nature of pharmaceutical supply vulnerability. (OECD, 2024; World Health Organization, 2020)

Systemic risk is amplified when API supply is concentrated in limited countries or suppliers. Global pharmaceutical production often depends on geographically concentrated manufacturing steps, and the OECD identifies concentration of API production in a small number of sites or regions as a potential vulnerability. In such a structure, even localized disruptions can have wider effects when alternative sources are unavailable or difficult to approve. (OECD, 2024; Christopher & Peck, 2004)

The third finding is that health crises transform API dependence from an industrial issue into a health security issue. During ordinary periods, API imports may appear manageable if supplies are stable and prices are predictable. During crises, however, export restrictions, transport disruption, demand surges, factory shutdowns, or currency volatility can rapidly expose the fragility of import-dependent systems. This is why API dependence must be considered within emergency preparedness and health resilience planning. (World Health Organization, 2007, 2020; Ivanov, 2020)

The fourth finding is that Indonesia has already taken policy steps toward pharmaceutical independence, but these steps need to be integrated into a resilience framework. The Ministry of Health has promoted change source facilitation, research and development, import trade governance, market assurance, and regulatory incentives to support domestic raw material production. These measures are important, but their effectiveness depends on coordination, implementation continuity, and adoption by pharmaceutical manufacturers. (Kementerian Kesehatan Republik Indonesia, 2023, 2025)

Change source policy is especially relevant because it addresses one of the practical barriers to reducing import dependence. Even when domestic APIs are available, finished medicine manufacturers must shift from imported to domestic raw material sources through a regulated process. The Ministry of Health has identified domestic production capacity for several widely used raw materials and has facilitated source changes to increase domestic usage. This illustrates how regulatory acceleration can serve as a bridge between domestic production and actual market adoption. (Kementerian Kesehatan Republik Indonesia, 2023)

The fifth finding is that domestic API capacity cannot stand alone without market assurance. API production is capital intensive, technology intensive, and quality sensitive. Domestic producers need predictable demand, procurement incentives, industry confidence, and regulatory support to survive against imported raw materials that may benefit from economies of scale. Without market assurance, domestic API facilities may exist but remain underutilized. (Badan Kebijakan Pembangunan Kesehatan, 2022; Kementerian Kesehatan Republik Indonesia, 2025)

Table 1. Priority Areas for Pharmaceutical Supply Chain Resilience

Priority area	Main vulnerability addressed	Expected resilience outcome

Domestic API capacity	Dependence on imported raw materials	Improved production continuity for priority APIs
Supplier diversification	Supplier and country concentration	Reduced exposure to single-source disruption
Strategic stockpiling	Sudden supply interruption during crisis	Emergency availability of critical APIs and medicines
Regulatory acceleration	Slow source switching and market adoption	Faster use of qualified domestic or alternative APIs
Research–industry integration	Weak innovation-to-production pathway	Long-term capability for API development and scale-up

The sixth finding is that supplier diversification is necessary even when domestic production is strengthened. Total pharmaceutical autarky is unrealistic, and the Ministry of Health has acknowledged that no country can make all raw materials by itself. Therefore, resilience requires a mixed strategy: domestic production for critical and feasible APIs, diversified foreign sourcing for other APIs, and strategic partnerships to reduce excessive concentration. (Kementerian Kesehatan Republik Indonesia, 2012a; OECD, 2024)

The seventh finding is that strategic stockpiling should be part of health security planning. A stockpile of critical APIs and essential medicines can provide short-term protection when supply chains are disrupted. However, stockpiling should be based on risk classification, expiry management, storage capacity, inventory rotation, and emergency distribution planning. Stockpiling without governance may become costly and inefficient; stockpiling with governance can become a critical resilience mechanism. (OECD, 2024; World Health Organization, 2020)

The eighth finding is that research–industry integration is a long-term prerequisite for API independence. Domestic API production requires not only factories but also scientific capability, process development, quality control, regulatory science, industrial chemistry, bioprocessing, and commercialization pathways. Universities and research institutions can support discovery and process development, but industry is needed for scale-up and market production. Regulators are needed to ensure quality, safety, and compliance. (Kementerian Kesehatan Republik Indonesia, 2012a, 2025)

The ninth finding is that pharmaceutical resilience requires measurable indicators. Activity-based indicators, such as the number of policy meetings or the existence of production facilities, are insufficient. Outcome-based indicators should include the number of critical APIs produced domestically, percentage of essential medicines supported by secure API sources, supplier diversification levels, stockpile coverage, change source approval timelines, and continuity of medicine availability during disruptions. (Bardach & Patashnik, 2020; OECD, 2024)

The tenth finding is that Indonesia's pharmaceutical resilience requires cross-sector coordination. The issue involves health policy, industrial policy, trade policy, research policy, regulatory policy, and fiscal policy. No single institution can address API dependence alone. Effective resilience requires coordination among the Ministry of Health, BPOM, Ministry of Industry, Ministry of Trade, BRIN, pharmaceutical state-owned enterprises, private pharmaceutical companies, universities, health providers, and procurement institutions. (Badan Kebijakan Pembangunan Kesehatan, 2022; Kementerian Kesehatan Republik Indonesia, 2025)

These findings show that API dependence is a complex policy problem that cannot be solved by a single intervention. Domestic production, supplier diversification, stockpiling, regulatory acceleration, and research–industry integration must be treated as complementary strategies. A resilience framework is needed because each strategy addresses a different layer of vulnerability. (Christopher & Peck, 2004; Ponomarov & Holcomb, 2009; OECD, 2024)

Based on the analysis, the article proposes that Indonesia should move from an import-substitution paradigm to a resilience-based pharmaceutical security paradigm. Import substitution asks how imported APIs can be replaced. Resilience asks which dependencies are critical, which disruptions are probable, which medicines are essential, which domestic capacities are feasible, which suppliers are reliable, and which emergency mechanisms can protect the population during crisis. (World Health Organization, 2024; OECD, 2024; Kementerian Kesehatan Republik Indonesia, 2025)

5. Discussion

The results indicate that API import dependence should be understood as a systemic vulnerability because it connects upstream industrial capacity with downstream health security outcomes. A disruption in API supply may not immediately appear as a public health problem, but it can quickly become one when essential medicine production slows, procurement contracts cannot be fulfilled, hospitals experience shortages, or patients lose access to treatment. This systemic link is the core reason why pharmaceutical supply chain resilience must be integrated into national health security planning. (OECD, 2024; World Health Organization, 2007, 2020)

The PSR-HS Framework is proposed as an integrated model for reducing API dependence and strengthening national health security. The framework consists of five mutually reinforcing elements: domestic API capacity, supplier diversification, strategic stockpiling, regulatory acceleration, and research–industry integration. Each element addresses a different vulnerability, and the value of the framework lies in their integration rather than their separate implementation. (Christopher & Peck, 2004; Ponomarov & Holcomb, 2009; Kementerian Kesehatan Republik Indonesia, 2025)

The first element, domestic API capacity, refers to the ability to produce priority APIs within Indonesia. This does not mean producing every API domestically. Instead, it means identifying critical APIs that are essential for public health, vulnerable to disruption, technically feasible, and strategically important. Domestic API development should prioritize medicines with high public health importance, high import vulnerability, and stable demand from national health programs. (Kementerian Kesehatan Republik Indonesia, 2023, 2025; Badan Kebijakan Pembangunan Kesehatan, 2022)

Domestic API capacity should be built through phased prioritization. The first phase can focus on high-volume and widely used APIs where domestic capability already exists or can be scaled quickly. The second phase can focus on APIs for essential medicines and chronic disease programs. The third phase can focus on more complex APIs requiring advanced chemistry, biotechnology, or specialized manufacturing. This phased approach is more realistic than attempting broad self-sufficiency at once. (Kementerian Kesehatan Republik Indonesia, 2012a, 2023, 2025)

The second element, supplier diversification, recognizes that domestic production cannot eliminate all external dependence. For APIs that cannot be produced domestically in the short term, Indonesia needs diversified international sources. Diversification reduces exposure to disruptions affecting a single supplier, country, port, transport route, or regulatory jurisdiction. It can also improve bargaining power and supply continuity. (OECD, 2024; Christopher & Peck, 2004; Ponomarov & Holcomb, 2009)

Supplier diversification should not be understood only as increasing the number of suppliers. Pharmaceutical sourcing requires quality assurance, regulatory documentation, Good Manufacturing Practice compliance, stability data, and long-term reliability. Therefore, diversification must include pre-qualified suppliers, dual sourcing strategies, regional cooperation, and contingency procurement mechanisms that can be activated during crisis without compromising safety and efficacy. (OECD, 2024; Kementerian Kesehatan Republik Indonesia, 2023)

The third element, strategic stockpiling, addresses short-term crisis protection. Stockpiling can reduce vulnerability when international supply is interrupted or demand suddenly increases. However, a pharmaceutical stockpile must be different from ordinary inventory accumulation. It requires risk-based selection, expiry rotation, cold chain requirements where needed, quality monitoring, financing mechanisms, and clear rules for release during emergencies. (World Health Organization, 2020; OECD, 2024)

A useful stockpiling model for Indonesia would focus on critical APIs and essential medicines linked to national health priorities. Priority should be given to medicines used in emergency care, infectious disease control, chronic disease management, maternal and child health, and public health programs. The stockpile should be integrated with procurement planning and e-catalog systems so that reserves are rotated before expiry and replenished systematically. (World Health Organization, 2020; OECD, 2024; Kementerian Kesehatan Republik Indonesia, 2025)

The fourth element, regulatory acceleration, is crucial because pharmaceutical resilience cannot be achieved if regulatory processes are too slow to support source changes during disruption. Regulatory acceleration does not mean lowering standards. It means creating faster, risk-based, and scientifically robust pathways for approving domestic APIs, change source applications, emergency procurement, and local-content incentives. (Kementerian Kesehatan Republik Indonesia, 2023, 2025; OECD, 2024)

Regulatory acceleration should include predictable timelines, clear documentation requirements, inter-agency coordination, and technical assistance for domestic producers. It should also include post-approval monitoring to ensure quality and safety. In this way, regulatory reform can accelerate resilience while preserving pharmaceutical quality and public trust. (Kementerian Kesehatan Republik Indonesia, 2023; World Health Organization, 2024)

The fifth element, research–industry integration, addresses the long-term innovation challenge. API production requires scientific knowledge, process optimization, quality control, environmental management, and industrial scaling. Research institutions may generate knowledge, but without industrial partners, market pathways, and regulatory support, research outputs may not become usable pharmaceutical inputs. Integration is therefore necessary to connect discovery, production, approval, procurement, and clinical use. (Kementerian Kesehatan Republik Indonesia, 2012a, 2025; Badan Kebijakan Pembangunan Kesehatan, 2022)

Research–industry integration should be organized around priority molecules rather than fragmented research agendas. A national API priority list can guide funding, laboratory development, pilot production, technology transfer, industry partnerships, and regulatory support. This would help align academic research with health system needs and market demand.

(Badan Kebijakan Pembangunan Kesehatan, 2022; Kementerian Kesehatan Republik Indonesia, 2025)

The PSR-HS Framework also requires governance integration. Pharmaceutical resilience involves multiple ministries and institutions. The Ministry of Health can define public health priorities and health security needs. BPOM can ensure regulatory quality and safety. The Ministry of Industry can support industrial capacity. The Ministry of Trade can manage import policy and supply diversification. BRIN and universities can support research. Pharmaceutical firms can execute production and commercialization. Procurement institutions can create market assurance. (Kementerian Kesehatan Republik Indonesia, 2025; Badan Kebijakan Pembangunan Kesehatan, 2022)

A key policy challenge is the tension between price efficiency and resilience. Imported APIs may be cheaper because of global economies of scale, while domestic APIs may require higher initial investment and market support. If procurement focuses only on lowest price, domestic API development may struggle. If procurement ignores efficiency, medicine costs may rise. A resilience-based procurement model should balance price, quality, supply continuity, domestic capacity, and crisis preparedness. (OECD, 2024; Christopher & Peck, 2004)

Another challenge is quality perception. BKPK has identified concerns about local product quality as one factor influencing import dependence in pharmaceutical and medical product contexts. Domestic API adoption requires confidence from finished medicine manufacturers, regulators, health providers, and procurement systems. Quality assurance, transparency, performance monitoring, and certification are therefore essential for building trust in domestic raw materials. (Badan Kebijakan Pembangunan Kesehatan, 2024; Kementerian Kesehatan Republik Indonesia, 2023)

The framework also implies that pharmaceutical resilience should be evaluated through measurable indicators. Domestic API capacity can be measured by number of priority APIs produced locally, production volume, capacity utilization, and quality certification. Supplier diversification can be measured by number of qualified suppliers and source countries. Stockpiling can be measured by months of coverage and stock rotation performance. Regulatory acceleration can be measured by approval timelines and change source adoption. Research–industry integration can be measured by pilot production, technology transfer, and commercialization outcomes. (Bardach & Patashnik, 2020; OECD, 2024)

The policy implications are significant. First, Indonesia should establish a national pharmaceutical supply resilience roadmap focused on priority APIs and essential medicines. Second, the country should classify APIs based on criticality, vulnerability, domestic feasibility, and health system impact. Third, the government should align procurement, regulation, industrial incentives, and research funding to support priority API development. (Kementerian Kesehatan Republik Indonesia, 2025; OECD, 2024)

Fourth, Indonesia should build a pharmaceutical supply risk dashboard that monitors API dependence, supplier concentration, import flows, inventory levels, medicine shortages, domestic capacity, and regulatory bottlenecks. Such a dashboard would support early warning, policy coordination, and crisis response. Fifth, the government should promote public–private partnerships for domestic API production, especially for APIs where domestic production is technically feasible and strategically important. (Bardach & Patashnik, 2020; World Health Organization, 2024)

Sixth, Indonesia should design strategic stockpiling for critical APIs and essential medicines as part of emergency preparedness. This stockpile should not be static; it should use rotation mechanisms, quality monitoring, and integration with routine procurement. Seventh, regulatory acceleration should continue through change source facilitation, clear approval pathways, and incentives for manufacturers that adopt domestic APIs with verified quality. (World Health Organization, 2020; Kementerian Kesehatan Republik Indonesia, 2023, 2025)

Eighth, Indonesia should strengthen regional and international cooperation without creating new dependence. ASEAN and other regional platforms can support information sharing, joint procurement options, manufacturing cooperation, and supply chain transparency. Strategic international cooperation can complement domestic production by improving diversified sourcing and emergency coordination. (OECD, 2024; World Health Organization, 2024)

The PSR-HS Framework therefore reframes pharmaceutical independence as resilience rather than isolation. The goal is not to eliminate all imports but to reduce dangerous dependence, protect essential medicine availability, and ensure that the health system can continue functioning during shocks. This approach is more realistic and strategically useful for a country with a large population, complex health needs, and an open economy. (Kementerian Kesehatan Republik Indonesia, 2012a; OECD, 2024; World Health Organization, 2007)

From a theoretical perspective, the framework contributes to health security literature by showing that health security depends not only on surveillance, hospitals, laboratories, and emergency response, but also on upstream industrial and supply chain capabilities. It also contributes to supply chain resilience literature by applying resilience concepts to APIs as critical health system inputs. (World Health Organization, 2007, 2024; Christopher & Peck, 2004; Ponomarov & Holcomb, 2009)

From a practical perspective, the framework can help policymakers identify where interventions should be targeted. If a medicine is essential and API dependence is high, the policy response may require

domestic capacity development and stockpiling. If domestic production is not feasible, supplier diversification and strategic partnerships may be more realistic. If domestic APIs exist but are not used, regulatory acceleration and procurement incentives may be the priority. (Kementerian Kesehatan Republik Indonesia, 2023, 2025; OECD, 2024)

The discussion also shows that pharmaceutical resilience must be treated as a continuous governance process. Resilience cannot be built only during crisis. It requires routine monitoring, investment, institutional learning, quality assurance, and policy coordination before disruption occurs. This aligns with WHO's view that resilient health systems must prepare, adapt, respond, recover, and maintain essential services in all contexts. (World Health Organization, 2024; World Health Organization, 2020)

Overall, Indonesia's API dependence represents both a vulnerability and an opportunity. It is a vulnerability because excessive import dependence exposes the health system to external shocks. It is an opportunity because policy attention to pharmaceutical resilience can strengthen domestic industry, improve health security, stimulate research, and increase preparedness for future crises. The PSR-HS Framework provides a structured way to turn this vulnerability into a strategic reform agenda. (Badan Kebijakan Pembangunan Kesehatan, 2022; Kementerian Kesehatan Republik Indonesia, 2025; OECD, 2024)

Figure 1. Conceptual flow of the PSR-HS Framework

Global disruptions → API import dependence → pharmaceutical supply vulnerability → medicine security risk → national health security risk → PSR-HS interventions → pharmaceutical supply chain resilience

6. Conclusion

This article has examined Indonesia's dependence on imported active pharmaceutical ingredients as a systemic risk to national health security. The analysis shows that Indonesia's pharmaceutical sector has important downstream manufacturing capacity but remains vulnerable at the upstream raw material level. This creates a structural gap between the ability to produce finished medicines and the ability to secure critical inputs during crises. (Kementerian Kesehatan Republik Indonesia, 2012a, 2012b; Badan Kebijakan Pembangunan Kesehatan, 2022)

Using qualitative policy analysis, the article identifies several key findings. First, API dependence can generate systemic risk because upstream disruptions can affect medicine production, procurement, hospital readiness, treatment continuity, and public health response. Second, health crises transform API dependence from an industrial issue into a national health security concern. Third, Indonesia has taken important policy steps toward pharmaceutical independence, including change source facilitation and support for domestic raw material production. (Kementerian Kesehatan Republik Indonesia, 2023, 2025; OECD, 2024; World Health Organization, 2020)

The article proposes the Pharmaceutical Supply Resilience for Health Security (PSR-HS) Framework as a conceptual policy model. The framework consists of domestic API capacity, supplier diversification, strategic stockpiling, regulatory acceleration, and research–industry integration. These five elements are mutually reinforcing and should be implemented as an integrated resilience strategy rather than separate sectoral programs. (Christopher & Peck, 2004; Ponomarov & Holcomb, 2009; Kementerian Kesehatan Republik Indonesia, 2025)

The main policy implication is that Indonesia should move from a narrow import-substitution approach toward a resilience-based pharmaceutical security strategy. This means identifying critical APIs, strengthening feasible domestic production, diversifying suppliers, building strategic reserves, accelerating regulatory pathways, integrating research and industry, and creating measurable resilience indicators. (Bardach & Patashnik, 2020; OECD, 2024; World Health Organization, 2024)

The limitation of this study is that it relies on secondary data and publicly available documents. It does not use confidential procurement data, proprietary industry information, or quantitative import-flow modeling. Future research should test the PSR-HS Framework through expert interviews, stakeholder validation, supply chain network analysis, and comparative studies with countries that have developed critical medicine strategies or API resilience policies. (Bowen, 2009; Creswell & Creswell, 2018; Patton, 2015)

Despite these limitations, the article contributes to pharmaceutical policy and health security studies by showing that API dependence is not simply a production issue. It is a systemic vulnerability that affects national resilience. Strengthening pharmaceutical supply chain resilience is therefore a strategic requirement for Indonesia's health security, crisis preparedness, and long-term public health sovereignty. (World Health Organization, 2007, 2024; OECD, 2024)

7. Extended Policy Framework and Implementation Logic

Table 1 presents the operational logic of the PSR-HS Framework. The framework begins from the recognition that global supply chain disruptions, pandemics, geopolitical tensions, export restrictions, currency volatility, and supplier concentration can affect the availability and price of APIs. These disruptions interact with Indonesia's high import dependence and create pharmaceutical supply chain vulnerability. The vulnerability then affects medicine security and national health security. The policy response is to strengthen domestic API capacity, diversify suppliers, build strategic stockpiles, accelerate regulation, and integrate research with industry. (OECD, 2024; World Health

Organization, 2024; Kementerian Kesehatan Republik Indonesia, 2025)

In operational terms, domestic API capacity should be developed through a national priority list. This list should identify APIs based on public health importance, import vulnerability, technical feasibility, market size, and strategic value. Such prioritization prevents resources from being spread too thinly and allows government support to focus on APIs that generate the highest health security benefit. (Badan Kebijakan Pembangunan Kesehatan, 2022; Kementerian Kesehatan Republik Indonesia, 2025)

Supplier diversification should be implemented through risk-based sourcing. This means that procurement and industry actors should map supplier concentration, country exposure, logistics routes, regulatory status, and quality history. APIs that are essential and highly concentrated should be subject to dual sourcing or multi-sourcing requirements when possible. This can reduce the probability that one disruption will halt production completely. (Christopher & Peck, 2004; OECD, 2024; Ponomarov & Holcomb, 2009)

Strategic stockpiling should be governed through a national critical medicine and API reserve system. The reserve should not include all medicines, but should prioritize those with high clinical importance, high shortage risk, and high impact on essential services. The stockpile should be connected to health emergency planning and should include release triggers, replenishment mechanisms, and accountability systems. (World Health Organization, 2020; OECD, 2024)

Regulatory acceleration should focus on scientifically justified speed. It should support faster review of domestic API adoption, change source applications, and priority medicines without weakening standards. The goal is not deregulation but responsive regulation. A strong regulator can simultaneously protect quality and enable resilience when pathways are transparent, risk-based, and coordinated with policy priorities. (Kementerian Kesehatan Republik Indonesia, 2023, 2025; World Health Organization, 2024)

Research–industry integration should create a pipeline from research to production. A national API innovation pipeline can include basic research, process development, pilot-scale production, quality validation, regulatory submission, industrial scale-up, procurement adoption, and post-market monitoring. This pipeline would help prevent research outputs from stopping at publication or prototype stage. (Kementerian Kesehatan Republik Indonesia, 2012a, 2025)

The PSR-HS Framework also requires governance indicators. Without indicators, resilience may remain rhetorical. Indicators should measure input, process, output, and outcome dimensions. Input indicators include investment in API production and research. Process indicators include approval timelines and supplier qualification. Output indicators include APIs produced domestically and stockpile coverage. Outcome indicators include shortage reduction, supply continuity, and crisis response performance. (Bardach & Patashnik, 2020; OECD, 2024)

A resilience-based strategy should also account for financial sustainability. Domestic API development may require incentives, tax support, public procurement commitments, and long-term contracts. However, support should be linked to performance, quality, and public health value. The state should avoid creating inefficient protectionism, but it should also recognize that pure price competition may underinvest in resilience. (OECD, 2024; Christopher & Peck, 2004)

The article's proposed framework can be used by government agencies to evaluate existing policies. For example, change source facilitation can be assessed under regulatory acceleration; domestic BBO production can be assessed under domestic API capacity; market assurance policies can be assessed under industrial sustainability; and crisis preparedness planning can be assessed under strategic stockpiling. This makes the framework practical for policy review. (Kementerian Kesehatan Republik Indonesia, 2023, 2025; Badan Kebijakan Pembangunan Kesehatan, 2022)

The framework can also be used by pharmaceutical companies. Firms can map which products depend on imported APIs, which suppliers are high risk, which alternatives are available, which domestic APIs meet quality requirements, and which products require regulatory change source planning. By doing so, companies can align commercial risk management with national health security objectives. (OECD, 2024; Ponomarov & Holcomb, 2009)

For researchers, the framework opens several future research agendas. Scholars can conduct empirical studies on API import networks, medicine shortage data, supplier concentration, domestic production feasibility, cost-resilience trade-offs, and stakeholder perceptions. Comparative studies can examine how other countries manage critical medicine dependence and whether their policies are adaptable to Indonesia. (Creswell & Creswell, 2018; Patton, 2015; OECD, 2024)

For health security planners, the framework provides a bridge between public health preparedness and industrial policy. Health security is often associated with surveillance, laboratories, emergency operations centers, and hospitals. This article argues that pharmaceutical raw material security should also be included because medicine availability is essential for maintaining health services during crisis. (World Health Organization, 2007, 2020, 2024)

Ultimately, pharmaceutical resilience should be treated as a national capability. A national capability is not built overnight; it requires sustained investment, institutional coordination, regulatory capacity, industrial learning, and continuous monitoring. Indonesia's policy direction already recognizes the importance of pharmaceutical independence. The next step is to

consolidate that recognition into a measurable resilience architecture. (Kementerian Kesehatan Republik Indonesia, 2025; Badan Kebijakan Pembangunan Kesehatan, 2022; OECD, 2024)

8. Policy Implications

The policy implications of the PSR-HS Framework begin with the need to define pharmaceutical resilience as a national priority rather than a temporary response to pandemic-era disruption. If resilience is treated only as a crisis response, policy momentum may weaken when global supply chains appear stable. A more strategic approach would institutionalize pharmaceutical resilience within health system transformation, industrial development, national emergency preparedness, and public procurement planning. (World Health Organization, 2024; Kementerian Kesehatan Republik Indonesia, 2025; OECD, 2024)

A national pharmaceutical resilience roadmap should identify priority APIs and essential medicines based on risk criteria. These criteria should include public health importance, clinical indispensability, current import dependence, supplier concentration, domestic feasibility, price sensitivity, and crisis relevance. Such a roadmap would help policymakers distinguish between APIs that should be domestically produced, APIs that should be diversified through international suppliers, and APIs that should be protected through stockpiling. (Bardach & Patashnik, 2020; OECD, 2024)

Indonesia should also develop a critical API list linked to the national essential medicines list and public health programs. The list should not be static because disease patterns, medicine use, technology, and global supply risks change over time. It should be reviewed periodically through collaboration between health authorities, clinicians, pharmacists, procurement agencies, pharmaceutical manufacturers, and supply chain experts. This would make pharmaceutical resilience more evidence-informed and clinically relevant. (World Health Organization, 2020, 2024; OECD, 2024)

Procurement policy is a central instrument for strengthening domestic API use. If public procurement systems reward only the lowest price, domestic API producers may face difficulty competing with large-scale foreign producers. A resilience-sensitive procurement model should consider price, quality, domestic value, supply continuity, supplier reliability, and health security benefits. This does not mean abandoning efficiency; it means recognizing resilience as a legitimate public value in procurement decisions. (OECD, 2024; Christopher & Peck, 2004)

Market assurance is especially important for domestic API production because API facilities require stable demand to justify investment. The government can support market assurance through long-term purchase commitments, preferential procurement for verified domestic APIs, transparent demand forecasting, and incentives for finished medicine manufacturers that adopt domestic raw materials. However, such support should be conditional on quality compliance, reliable supply, and cost discipline to avoid inefficiency. (Kementerian Kesehatan Republik Indonesia, 2025; Badan Kebijakan Pembangunan Kesehatan, 2022)

Indonesia should strengthen regulatory science capacity to support pharmaceutical resilience. Regulatory science is needed to evaluate API quality, source changes, bioequivalence implications, stability data, process validation, and post-approval changes. If regulatory capacity is weak, acceleration may either become unsafe or remain slow. A strong regulator can enable faster resilience responses while maintaining public trust in medicine quality. (Kementerian Kesehatan Republik Indonesia, 2023; World Health Organization, 2024)

Another implication is the need for real-time pharmaceutical supply chain visibility. A resilience dashboard could integrate data on API imports, domestic production capacity, stock levels, supplier concentration, procurement contracts, medicine shortages, and regulatory approvals. Such a dashboard would not need to disclose confidential commercial data publicly, but it should enable authorized policymakers to detect vulnerabilities and coordinate responses before shortages become visible to patients. (OECD, 2024; Bardach & Patashnik, 2020)

Supply chain visibility should be connected to early warning mechanisms. Early warning indicators may include shipment delays, sudden price increases, export restrictions, supplier quality alerts, currency volatility, disease outbreaks, geopolitical events, and abnormal demand patterns. By linking these indicators with priority medicine lists, Indonesia can move from reactive shortage management to anticipatory risk governance. (Ivanov, 2020; OECD, 2024; World Health Organization, 2020)

The pharmaceutical industry also needs incentives to adopt resilience practices. Firms may hesitate to change API sources because of regulatory burden, cost uncertainty, quality risk, and supply reliability concerns. Government support can reduce these barriers through technical assistance, clear regulatory pathways, shared testing facilities, tax incentives, and procurement signals. Industry participation is essential because resilience cannot be imposed only through policy documents. (Kementerian Kesehatan Republik Indonesia, 2023, 2025; Badan Kebijakan Pembangunan Kesehatan, 2022)

Human resource development is another important component. API production and pharmaceutical supply chain governance require pharmacists, chemists, chemical engineers, quality assurance specialists, regulatory scientists, logistics planners, procurement specialists, and health security analysts. Strengthening human capital would support both domestic API production and risk-based supply chain management.

(World Health Organization, 2024; Kementerian Kesehatan Republik Indonesia, 2012a)

Environmental and safety governance should also be considered. API manufacturing can involve chemical processes that require strict environmental controls, waste management, occupational safety, and compliance with industrial standards. Domestic API development should therefore be aligned with environmental sustainability and industrial safety, not only production volume. Resilience should not create new health or environmental risks. (World Health Organization, 2024; OECD, 2024)

Regional cooperation can complement domestic resilience. Indonesia can work with ASEAN partners to share information on medicine shortages, critical APIs, supplier risk, regulatory practices, and emergency procurement. Regional cooperation can also support pooled demand signals for certain critical medicines, although such arrangements require careful governance. ASEAN-based cooperation would be consistent with Indonesia's broader interest in regional health security and supply chain stability. (World Health Organization, 2007, 2024; OECD, 2024)

The private sector should be engaged through structured public–private dialogue. Pharmaceutical companies possess operational knowledge about supplier reliability, production constraints, regulatory barriers, and market feasibility. Government agencies possess policy authority and public health priorities. A structured forum can align these perspectives, identify bottlenecks, and generate practical solutions. Without such dialogue, policies may be technically sound but difficult to implement. (Bardach & Patashnik, 2020; Patton, 2015)

The PSR-HS Framework also implies that Indonesia should build scenario planning capacity. Scenario planning can examine how the health system would respond if a major API supplier shuts down, a major export country restricts shipments, a pandemic increases demand for specific medicines, or currency depreciation raises import costs. Such exercises would reveal gaps in procurement, stockpiling, regulation, and logistics before a real crisis occurs. (World Health Organization, 2020, 2024; Ivanov, 2020)

Education and research institutions can support scenario planning and policy evaluation. Universities can conduct supply chain mapping, shortage risk modeling, domestic production feasibility studies, and policy evaluation. Research institutions can support process development for priority APIs. Collaboration with industry can ensure that research questions are linked to real production needs and public health priorities. (Kementerian Kesehatan Republik Indonesia, 2012a, 2025; Creswell & Creswell, 2018)

Finally, pharmaceutical resilience should be treated as part of national resilience. Health security depends on many systems outside the health sector, including trade, industry, transportation, finance, research, regulation, and diplomacy. API dependence illustrates this interdependence clearly. A medicine shortage may originate from a factory abroad, a shipping route disruption, a quality problem, a currency shock, or a domestic regulatory delay. Therefore, the response must be multisectoral. (World Health Organization, 2007, 2024; OECD, 2024)

9. Limitations and Future Research Agenda

Future research should empirically map Indonesia's API import network by molecule, supplier, country of origin, manufacturer, formulation site, and finished product category. Such mapping would allow policymakers to distinguish between apparent diversification and real diversification. A medicine may have several brand names and manufacturers but still depend on the same API source, creating hidden concentration risk. (OECD, 2024; Bowen, 2009)

Another future research agenda is to calculate criticality scores for APIs used in Indonesia. A criticality score could combine public health importance, usage volume, shortage history, supplier concentration, domestic feasibility, and availability of therapeutic alternatives. This would enable more precise prioritization than general statements about pharmaceutical independence. (Bardach & Patashnik, 2020; World Health Organization, 2020)

Stakeholder research is also needed. Interviews with policymakers, regulators, pharmaceutical manufacturers, pharmacists, hospital procurement units, health economists, and patient representatives could validate the PSR-HS Framework and identify implementation barriers. Stakeholder perspectives are especially important because pharmaceutical resilience depends on the behavior of many actors, not only government policy. (Creswell & Creswell, 2018; Patton, 2015)

Quantitative modeling can complement qualitative policy analysis. Researchers can model the impact of supplier disruption, exchange rate movements, export restrictions, or sudden demand increases on API availability and finished medicine production. Such modeling can support scenario planning and help determine the appropriate size of strategic stockpiles. (Ivanov, 2020; OECD, 2024)

Comparative studies can examine how other countries design critical medicine strategies, API reserves, supplier diversification policies, and domestic production incentives. These comparisons should not be copied mechanically because Indonesia has its own industrial structure, fiscal capacity, regulatory system, and health needs. However, comparative learning can help Indonesia avoid policy mistakes and identify adaptable instruments. (OECD, 2024; World Health Organization, 2024)

Future research should also examine the economics of resilience. Domestic API production may increase short-term costs, while supply disruption may generate high social and health costs. Cost-benefit analysis

should therefore include avoided shortage costs, emergency procurement savings, treatment continuity, industrial learning, and national health security value. This would provide a more complete picture than procurement price alone. (Bardach & Patashnik, 2020; OECD, 2024)

Researchers should also investigate the relationship between pharmaceutical resilience and universal health coverage. Medicine shortages can weaken access to care even when insurance coverage exists. A health financing system cannot deliver effective care if essential medicines are unavailable. Therefore, medicine security should be integrated into broader health system performance indicators. (World Health Organization, 2020, 2024)

The PSR-HS Framework should be tested through case studies of specific APIs or therapeutic classes. For example, researchers could analyze paracetamol, antibiotics, cardiovascular medicines, diabetes medicines, or emergency medicines. Case studies would reveal whether each API requires domestic production, supplier diversification, strategic stockpiling, regulatory acceleration, or a combination of all five elements. (Kementerian Kesehatan Republik Indonesia, 2023; OECD, 2024)

Longitudinal research is also important. Pharmaceutical resilience cannot be measured at one point in time because supply chains evolve. A longitudinal study could examine whether policy interventions reduce import dependence, increase domestic API use, improve supply continuity, and reduce shortage risk over several years. This would help determine whether policy initiatives create sustainable resilience or only temporary improvements. (Creswell & Creswell, 2018; Patton, 2015)

Finally, future research should explore governance models for multisectoral pharmaceutical resilience. Since API dependence involves health, industry, trade, finance, regulation, and research, the institutional design of coordination matters. Research can compare centralized, networked, and hybrid governance models to determine which arrangement best supports fast decision-making, accountability, technical quality, and implementation continuity. (Bardach & Patashnik, 2020; World Health Organization, 2024)

10. Implementation Roadmap

An implementation roadmap can translate the PSR-HS Framework into staged action. In the short term, Indonesia should conduct a national API vulnerability audit. The audit should identify which essential medicines depend on imported APIs, which suppliers are most concentrated, which molecules have domestic alternatives, and which products are most vulnerable during emergencies. The result should be a ranked list of critical APIs requiring immediate policy attention. (OECD, 2024; Bardach & Patashnik, 2020)

In the medium term, Indonesia should align regulatory acceleration with industrial readiness. Domestic API producers need clear standards, technical support, and predictable review timelines, while finished medicine manufacturers need confidence that domestic APIs meet quality and supply requirements. The Ministry of Health's change source facilitation provides an important starting point, but it should be expanded into a systematic national pathway for priority APIs. (Kementerian Kesehatan Republik Indonesia, 2023, 2025)

In the long term, Indonesia should build a pharmaceutical innovation ecosystem that links research, production, regulation, procurement, and health security planning. This ecosystem should not rely only on individual projects. It should create institutional routines for selecting priority molecules, funding process research, validating quality, supporting scale-up, securing demand, and monitoring resilience outcomes. (Kementerian Kesehatan Republik Indonesia, 2012a, 2025; World Health Organization, 2024)

The roadmap should also include accountability mechanisms. Each priority API should have a responsible institutional lead, implementation timeline, risk register, performance indicator, and review schedule. Without accountability, resilience policy may remain aspirational. With accountability, the government can identify bottlenecks early and adjust policy instruments before supply vulnerabilities become medicine shortages. (Bardach & Patashnik, 2020; OECD, 2024)

A practical roadmap should therefore follow three phases: vulnerability identification, resilience intervention, and outcome evaluation. Vulnerability identification maps critical APIs and risks. Resilience intervention applies domestic capacity, supplier diversification, stockpiling, regulatory acceleration, and research–industry integration. Outcome evaluation measures whether medicine availability, supply continuity, and crisis preparedness improve over time. (Christopher & Peck, 2004; Ponomarov & Holcomb, 2009; World Health Organization, 2024)

This staged roadmap reinforces the article's central argument: pharmaceutical resilience is not achieved by one policy instrument alone. It requires a coordinated architecture that links upstream production capability with downstream medicine security. If Indonesia can institutionalize this architecture, API import dependence can be reduced not only as an industrial target but as a measurable contribution to national health security. (Badan Kebijakan Pembangunan Kesehatan, 2022; Kementerian Kesehatan Republik Indonesia, 2025; OECD, 2024)

11. Managerial and Institutional Implications

For pharmaceutical managers, the PSR-HS Framework encourages a shift from procurement efficiency to strategic supply assurance. Firms should classify API suppliers by risk, prepare approved alternative sources where possible, document quality and regulatory requirements for source switching, and

coordinate with regulators before disruption occurs. Such preparation can reduce delays when global supply conditions change suddenly. (OECD, 2024; Ponomarov & Holcomb, 2009)

For hospital and public procurement managers, the framework highlights the need to connect medicine demand planning with upstream API risk. Procurement units often see shortages only at the finished product stage, but shortages may originate much earlier in API manufacturing or logistics. Better coordination between procurement, manufacturers, and regulators can improve early warning and reduce the risk of sudden service disruption. (World Health Organization, 2020; OECD, 2024)

For regulators, the framework supports the development of risk-based pathways for priority medicines and critical APIs. Regulatory systems must protect public safety, but they also need the capacity to respond quickly when supply disruptions threaten essential services. The challenge is to maintain quality standards while improving responsiveness, transparency, and coordination with health security priorities. (Kementerian Kesehatan Republik Indonesia, 2023; World Health Organization, 2024)

For policymakers, the framework clarifies that pharmaceutical resilience should be measured as a public value. The benefits of resilience may not always appear in ordinary procurement prices, but they become visible when crises occur and medicine access is threatened. Policy evaluation should therefore include avoided shortages, continuity of care, emergency preparedness, and national health security outcomes. (Bardach & Patashnik, 2020; OECD, 2024)

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