National Drug Resilience within the Legal Framework: An Analysis of Regulation and Implementation of Law Number 17 of 2023

Raymond R. Tjandrawinata[1], Ina Heliany[2]
[1]Atma Jaya Catholic University of Indonesia, Jakarta, Indonesia
[2]IBLAM University, Jakarta, Indonesia
Email: raytjan@yahoo.com

Abstract

National drug resilience is a fundamental pillar for achieving health independence and sovereignty in Indonesia. Strengthening this resilience has become a strategic mandate outlined in Law No. 17 of 2023 on Health, emphasizing the critical role of producing pharmaceuticals, vaccines, medical devices, and natural-based medicines to support the national healthcare system. This article examines the regulatory aspects, implementation, and challenges of realizing national drug resilience through a normative juridical approach. The integration of progressive legal theory, utilitarianism, and the welfare state model is the primary analytical framework for evaluating policy effectiveness. This approach is reinforced by a human rights perspective, particularly the right to health as enshrined in Article 28H of the 1945 Constitution and international frameworks such as ICESCR. The findings highlight that synergy among adaptive legal policies, strengthening biodiversity-based research and innovation, and supporting local industries are key to reducing dependence on imported materials and enhancing global competitiveness. This article contributes to local legal literature by integrating legal theory with human rights frameworks in the context of pharmaceutical policy while offering practical recommendations for supporting sustainable drug resilience policies. It provides a theoretical and strategic foundation for bolstering the national healthcare system through an inclusive and progressive legal approach.

Keywords: *National Drug Resilience, Pharmaceutical Regulation, Health Law, Legal Regulation, Policy Implementation.*

A. INTRODUCTION

National drug resilience is one of the primary pillars in ensuring the sustainability of healthcare services and protecting society from potential health crises. It encompasses not only the availability of medicines but also the assurance of quality, safety, and efficacy of pharmaceutical products consumed by the public. In an increasingly complex global context, national drug resilience becomes critically important as a strategic effort to reduce dependence on external resources and strengthen domestic capacity. Law No. 17 of 2023 on Health provides a robust legal foundation for enhancing the independence and resilience of Indonesia's healthcare system. Articles 101 to 103 of the law direct the development of an inclusive and competitive pharmaceutical ecosystem (Gamalliel & Fuady, 2024). However, implementing these policies faces several challenges, including weak pharmaceutical infrastructure, limited access to modern technology, inadequate investment in research and development, and a lack of incentives for local industry players.

In the context of legal theory, the welfare state model proposed by Friedmann is relevant to this effort (Gough, 1978). This approach positions the government as the primary actor responsible for providing universal access to healthcare services, including affordable and high-quality medicines. The state bears both moral and legal obligations to ensure that all citizens have access to basic health needs, including essential medicines. Additionally, the progressive legal theory Satjipto Rahardjo (2002) developed offers a more adaptive and dynamic perspective.

According to Rahardjo, law must be able to respond to contemporary challenges such as globalization, technological advancements, and global market dynamics. In the context of national drug resilience, this theory emphasizes the importance of regulations that support innovation and creativity. Thus, national drug resilience is not merely about creating a system capable of withstanding external shocks but also about building a self-reliant, innovative, and sustainable ecosystem. Through the synergy of adaptive legal regulations, strengthening the local pharmaceutical industry, and comprehensive support for research and development, national drug resilience can become a cornerstone in achieving true health sovereignty.

B. METHOD

This article employs a normative juridical approach, analyzing legal norms and regulations relevant to supporting national drug resilience. This approach aligns with the research objective of evaluating the pharmaceutical sector's legal foundation and policy implementation. Within this framework, the study examines various legal instruments that form the basis for health sector policies, including regulations governing pharmaceuticals, vaccines, medical devices, and natural-based medicines.

The analysis begins with an in-depth examination of Law No. 17 of 2023 on Health, which serves as the main foundation for strengthening national pharmaceutical resilience. Articles 101 to 103 of this law provide strategic directives to promote self-reliance in pharmaceutical production and reduce dependency on imported raw materials. Furthermore, the law underscores the importance of developing medicines based on natural resources and establishing an inclusive and competitive pharmaceutical ecosystem. The analysis extends to the Minister of Health Regulation on Fitofarmaka (phytopharmaceuticals) also forms a key focus of this study. This regulation provides operational guidance for developing products based on local biodiversity, including production standards and incentives for research and innovation in traditional medicines.

The article employs qualitative descriptive analysis to interpret the legal framework established in various legislative instruments (Cane and Kritzer, 2010). This analysis seeks to understand how these policies are implemented in practice and the obstacles encountered during their execution. Secondary data include scientific journals, government agency reports, and publications from the pharmaceutical industry. These sources enrich the analysis by providing empirical insights into the effectiveness of current regulations and the dynamics affecting their implementation.

Theoretically, this article integrates multiple legal frameworks to provide a robust analytical foundation. Progressive legal theory by Satjipto Rahardjo is used to evaluate the adaptability of regulations to contemporary challenges, such as globalization and technological innovation. Utilitarianism complements this approach by highlighting the importance of policies that maximize societal benefits, particularly regarding the accessibility and affordability of medicines. On the other hand, Friedmann's welfare state concept emphasizes the government's active role in ensuring citizens' health rights through inclusive interventions. By combining a normative approach with qualitative descriptive analysis, this article comprehensively evaluates national drug resilience regulations. This method identifies opportunities and challenges in policy implementation while offering practical recommendations to strengthen Indonesia's healthcare system. This evaluation contributes to a deeper understanding of the importance of adaptive and innovative legal regulations in creating sustainable pharmaceutical resilience.

C. RESULTS AND DISCUSSION

1. Dependence on Imported Raw Materials: A Pressing Structural Issue

The findings show that implementing national drug resilience regulations faces significant challenges, including the high dependence on imported raw materials. More than 90% of the active pharmaceutical ingredients (APIs) used in Indonesia are imported, primarily from India and China (Badan POM, 2023). In 1Q24, the pharmaceutical industry's imports were USD 2.1 bn, or slightly rose by 2.7% yoy from 1Q23, potentially due to increased demand from the domestic market (Permata Bank, 2024). This immense dependence reflects the weakness of the local pharmaceutical industry's infrastructure, particularly in the production of high-quality raw materials. This dependency is not only caused by a lack of investment in the pharmaceutical sector but also limited access to cutting-edge technology for raw material production. According to Hermawan et al. (2023), over 70% of pharmaceutical factories in Indonesia still rely on conventional technologies that do not meet international standards, making it difficult for local producers to compete in both domestic and international markets. Additionally, the lack of incentives for local industry players exacerbates the situation, leaving many pharmaceutical companies reluctant to invest in expanding production capacity. As a result, Indonesia faces significant risks regarding the stability of the national drug supply, particularly during emergencies or global crises, such as the COVID-19 pandemic.

The COVID-19 pandemic provided a concrete example of the impact of this dependency. Factory shutdowns in India and China due to activity restrictions during the pandemic caused significant disruptions in the global supply chain of pharmaceutical raw materials. The raw material shortages in 2020 and 2021 led to a surge in drug prices in Indonesia by up to 30% for some essential products (Rina, 2020). This situation highlights the importance of diversifying raw material sources and developing domestic production capacity for national pharmaceutical resilience. Although the government has issued policies encouraging local raw material

production, their implementation remains far from optimal. The main obstacles are structural barriers such as weak cross-agency coordination, limited budgets to support research and development, and cumbersome regulations (Tijaja and Faisal., 2014).

The government has also not fully utilized fiscal incentives to attract private sector investment in developing local pharmaceutical industries. According to BPOM report (2023), domestic production capacity can only meet about 10% of national demand, far below the expected target. The latest report by the Permata Bank (2024) stated that high import dependence increases production costs and reduces the competitiveness of local pharmaceutical products in the global market. Therefore, a strategic approach is needed, including government support through subsidies, technology transfer from advanced countries, and enhancing human resource capacity in the pharmaceutical sector.

2. Barriers to the Implementation of Local Production Policies

Although the government has issued various policies to encourage the local production of pharmaceutical raw materials, their implementation remains far from optimal. Structural barriers are the main obstacles to the realization of these policies. One of the biggest challenges is the weak coordination between government agencies. Poor coordination often results in overlapping policies and slow licensing processes required to support investment in local pharmaceutical raw material production (Hermawab et al., 2023). This becomes a significant barrier for industry players to initiate or expand their production capacity. The lack of fiscal incentives for local producers also represents a major hindrance. Most pharmaceutical industry stakeholders rely on government support through tax exemptions, research subsidies, or other incentives to reduce production costs. However, the existing fiscal policies have not been attractive enough for domestic or international investors to develop the raw material industry in Indonesia.

According to The Prakarsa (2020), the tax incentives offered by the government are still below the average of other ASEAN countries, prompting investors to prefer countries such as Vietnam or Thailand to set up pharmaceutical raw material factories. Limited access to advanced technology also becomes a significant challenge in implementing this policy. Indonesia's raw material production technology is mostly conventional and does not meet international standards. Local pharmaceutical raw material production can only meet about 10–15% of national demand. This shows that most raw materials used in the pharmaceutical industry in Indonesia still need to be imported. In this context, the gap in local production capacity creates dependency on imports and increases production costs, which are ultimately passed on to consumers. In addition to technical barriers, the pharmaceutical sector’s lack of skilled human resources also becomes an urgent issue (Hermawan, 2023).

The pharmaceutical raw material industry requires a workforce with specialized skills, particularly in using advanced technology and an understanding of international standards. Local raw material research and development subsidies

should be a government priority to encourage innovation in this sector. Additionally, structured and sustainable technology transfer programs from advanced countries should be initiated to accelerate the modernization of production technologies in Indonesia. Support in the form of tax exemptions or tax holidays could also attract investors to invest in developing the local pharmaceutical raw material industry in Indonesia. Finally, human resource development through intensive training and cooperation with educational institutions both domestically and abroad should be an integral part of this strategy (Pradana and Arijanto, 2024). A more strategic and integrated policy implementation can help Indonesia reduce dependency on imported pharmaceutical raw materials and improve the competitiveness of local products in the global market. Thus, national pharmaceutical resilience can be achieved while supporting the government's vision of building national health independence.

3. Development of Natural-Based Medicines: Untapped Potential

Indonesia, with its biodiversity of over 30,000 plant species, has great potential to become a global producer of phytopharmaceuticals. This potential is further reinforced by the fact that many native plant species in Indonesia contain bioactive compounds that can be developed into raw materials for both modern and traditional medicines (Tjandrawinata, 2020). However, to date, this natural wealth has not been optimally utilized on an industrial scale. Natural-based products that have successfully entered the national pharmaceutical market are still very few compared to the existing potential. Structural and policy barriers often serve as the main obstacles in developing phytopharmaceuticals. The main barriers to the utilization of phytopharmaceuticals in Indonesia include complex regulations and slow licensing processes. Although regulations are designed to protect consumers and ensure product safety, bureaucratic complexity often hinders innovation. According to Tjandrawinata (2020), clinical trial requirements and certifications for natural-based products are much stricter compared to countries with advanced phytopharmaceutical industries, such as India and China. This makes it difficult for local industry players to compete in both domestic and international markets. The lengthy licensing process also increases production costs, making natural-based products less competitive than chemical-based pharmaceutical products. Furthermore, the lack of government support in the form of incentives and funding for phytopharmaceutical research and development is a significant barrier. Academics conduct most research in Indonesia without adequate industry involvement.

In contrast, in countries like India, the government actively provides subsidies and tax incentives for phytopharmaceutical research involving partnerships between universities and pharmaceutical companies. In Indonesia, limited research funding causes many projects to stop at the early stages without progressing to commercialization. The lack of modern research facilities and limited skilled human resources in natural products pharmacology compounds this. The lack of collaboration between academics, industry, and government is also a major hindrance. Effective synergy between these three parties is crucial to creating an innovation

ecosystem that supports the development of phytopharmaceuticals. However, in Indonesia, such collaboration is still very limited. Many academics work in isolation without industry support, while pharmaceutical companies avoid the risk of investing in research without guaranteed success. On the other hand, the government often only acts as a regulator without providing a platform to encourage closer partnerships. Without strong synergy, the development of biodiversity-based products will continue to face significant barriers, and Indonesia's vast potential in this area will remain untapped.

To overcome these challenges, a holistic approach covering various aspects is required. First, regulatory reforms must be undertaken to simplify the licensing process without compromising safety and quality standards. For example, implementing a fast-track approval process for natural-based products that meet certain criteria could accelerate phytopharmaceutical commercialization. Second, the government needs to increase investment in phytopharmaceutical research and development. This can be done by providing research grants focused on exploring natural materials, building modern research facilities, and offering tax incentives for pharmaceutical companies investing in natural product development. Third, strengthening collaboration between academics, industry, and government should be a priority. The government can act as a facilitator by creating platforms that allow these three parties to collaborate on focused research projects.

For example, in India, the Council of Scientific and Industrial Research (CSIR) works with local pharmaceutical companies and academic institutions to develop phytopharmaceuticals, which are now a key part of the country's pharmaceutical industry (Government of India, 2023). Lastly, Indonesia must leverage global networks to accelerate the development of phytopharmaceuticals. Partnerships with advanced countries that possess advanced pharmaceutical technologies can assist Indonesia in technology transfer and capacity-building. Additionally, promoting Indonesian natural products in international markets through trade fairs and economic diplomacy initiatives can enhance the global competitiveness of Indonesian natural products.

Through regulatory reforms, increased investment, strengthened collaboration, and the utilization of global networks, Indonesia can fully harness its biodiversity potential and become a global leader in phytopharmaceutical production. These steps will not only support economic growth but also increase national independence in providing natural-based medicines. In the context of utilizing Indonesia's biodiversity for the development of natural-based medicines, more proactive and targeted policies are necessary to accelerate the commercialization of phytopharmaceutical products. Various strategic steps must be taken to address regulatory barriers, enhance industrial capacity, and open broader market access.

Simplifying licensing processes is an urgent initial step to accelerate the commercialization of natural-based medicines. Regulatory frameworks in Indonesia are often multilayered, with licensing timelines averaging 1–2 years for a single phytopharmaceutical product (Tjandrawinata, 2020). Approaches such as fast-track

approval, which have been implemented in countries like India and China, could provide a solution to reduce time barriers without compromising product safety and quality standards. Focused regulations, such as implementing a "one-stop service" policy for all administrative processes related to natural-based product licensing, can also significantly improve efficiency and accelerate time-to-market. In addition to streamlining licensing processes, the regulatory framework must be strengthened to provide clearer legal foundations and support innovation. This effort includes establishing quality standards aligned with international market needs and harmonizing regulations with global standards, such as those set by the WHO. Supportive regulations should also recognize the uniqueness of Indonesia's natural-based products, including geographical indication protections and intellectual property rights. This approach would not only provide Indonesian natural-based products with a competitive edge in international markets but also protect the nation's biodiversity.

Providing fiscal and non-fiscal incentives to local industries is a key strategy for encouraging participation in the development and commercialization of natural-based medicines. The government can offer tax holidays to companies investing in phytopharmaceutical research and development, subsidies for clinical trial costs, or duty exemptions for laboratory equipment and modern technologies. Additional incentives, such as awards for companies successfully bringing natural-based products to global markets, could further motivate industry players.

International collaboration is crucial for accelerating the development of modern technologies supporting natural-based medicines' production. Partnerships with advanced countries possessing expertise in extraction, formulation, and standardization technologies can enable Indonesia to adopt proven efficient methods. For instance, collaborations between Indonesian research institutions and organizations like CSIR-India or the China Academy of Chinese Medical Sciences, which have extensive experience in phytopharmaceutical development, can serve as valuable models (Lubis et al., 2023). Technology transfer through structured international partnerships could also enhance the capacity of Indonesia's human resources. Intensive training programs and technology transfer initiatives from countries excelling in natural product pharmaceuticals could equip Indonesian professionals with the skills needed to improve production quality and quantity.

Ensuring successful commercialization requires enhancing the production capacity of natural-based medicines through the construction of modern factories that comply with Good Manufacturing Practice (GMP) standards. Collaborative efforts between the government and private sector can support the establishment of large-scale production facilities equipped with advanced technologies for natural product extraction and processing. Additionally, the creation of industrial zones dedicated to natural-based products could catalyze the development of an ecosystem conducive to phytopharmaceutical growth. Active promotion of Indonesian natural-based products in international markets should also be prioritized. The government can facilitate this effort by organizing international trade fairs, establishing bilateral

cooperation for product marketing, and supporting local entrepreneurs in obtaining international certifications, such as halal or organic labels. Strengthening the branding of Indonesian natural-based products is essential to attract global market interest.

Creating a sustainable innovation ecosystem requires strengthened synergy among academia, industry, and government. The government can facilitate partnerships through joint research grant programs, while academia can contribute evidence-based studies to support product innovation. Industry players, on the other hand, can play a role in funding and commercializing products. With strong synergy, barriers that have hindered phytopharmaceutical development can be effectively addressed.

4. Pharmaceutical Innovation Ecosystem Weaknesses

The pharmaceutical innovation ecosystem in Indonesia faces significant challenges that hinder the development of this sector as a critical pillar of the national healthcare system. Despite Indonesia's considerable potential in human resources and biodiversity, support for research and development (R&D) in the pharmaceutical sector remains highly limited. Funding for research from both government and private sectors falls far short of the needs. Data show that pharmaceutical R&D spending in Indonesia amounts to only about 0.25% of Gross Domestic Product (GDP), far below countries such as South Korea (4.3%) and Singapore (2.2%) (Huda et al., 2020). The lack of research infrastructure also stands as one of the main obstacles. Many research institutions in Indonesia still use inadequate facilities to conduct advanced pharmaceutical research. For instance, equipment for analyzing pharmaceutical active ingredients or tools for molecular simulation are often unavailable. Consequently, pharmaceutical research focuses on generic or simple formulations rather than developing innovative new drugs.

Satjipto Rahardjo (2002) noted that this situation reflects a lack of attention to innovation, prioritizing mass production over creating added value through research. The lack of cross-sector collaboration further exacerbates these obstacles. Collaboration between academia, industry, and government is crucial to creating a conducive innovation environment. Currently, most pharmaceutical research in Indonesia is conducted by universities and research institutions without direct involvement from the pharmaceutical industry. Meanwhile, pharmaceutical companies tend to focus on the production and distribution of drugs without heavily investing in R&D. The government, as the main stakeholder, has also not provided sufficient incentives to encourage such collaboration.

Limited funding is also a key factor hindering innovation in Indonesia's pharmaceutical sector. Most pharmaceutical research budgets come from universities or public research institutions, which are often insufficient for large-scale research projects. In developed countries, most pharmaceutical R&D funding comes from the private sector. However, in Indonesia, private investment in this area remains very low due to high risks and a lack of market assurance for innovative products. Additionally, complex and inconsistent regulations hinder the innovation process.

Many researchers face difficulties obtaining permits for clinical trials, which can take years. This process slows the development of new drugs and significantly increases costs, causing much pharmaceutical research to stop at early stages.

To address these challenges, a comprehensive strategy encompassing several aspects is required. First, the government needs to increase the budget allocation for R&D in the pharmaceutical sector. These funds can be used to build modern research infrastructure, support scholarship programs for young researchers, and provide incentives for pharmaceutical companies investing in new drug development. Second, regulations related to clinical trials and drug licensing need to be simplified without compromising safety and quality standards. For example, implementing fast-track pathways for clinical trials can help accelerate the development of innovative drugs. Third, establishing pharmaceutical innovation centers can be a solution to address research fragmentation. These centers can facilitate collaboration among universities, industry, and government while providing access to advanced research facilities. Additionally, the government can establish international partnerships for technology transfer and capacity building in the pharmaceutical sector. Fourth, promoting and supporting the development of phytopharmaceuticals based on Indonesia's biodiversity should be a priority. By utilizing unique biological resources, Indonesia can develop high-value drugs with significant potential in the global market. To achieve this, the government needs to provide supportive regulatory frameworks and incentives for pharmaceutical companies to explore natural materials. By building a stronger pharmaceutical innovation ecosystem, Indonesia can not only meet domestic needs but also compete in international markets. These measures will significantly contribute to national pharmaceutical independence and enhance the global competitiveness of Indonesia's pharmaceutical industry.

5. Strategic Approaches for National Drug Resilience

National drug resilience is one of the key elements in ensuring public access to safe, effective, and affordable medicines. However, achieving this requires an integrated strategic approach. Several strategic steps can be taken to address the challenges faced by the national pharmaceutical industry, particularly in production, innovation, and distribution.

Strengthening investment in research and development (R&D) is a fundamental step to create an innovative and self-reliant pharmaceutical ecosystem. Currently, R&D funding in Indonesia is very limited, with the pharmaceutical sector contributing less than 1% of total national investment in research (Huda et al., 2020). The government needs to increase budget allocations to support research on developing new drugs, particularly in phytopharmaceuticals and biosimilars, which have significant potential in domestic and international markets. In addition to government funding, the private sector must also be encouraged to invest in R&D. Financial incentives, such as tax reductions of up to 200% for research expenditures, have proven effective in countries like Singapore and South Korea. Similar policies

can be applied in Indonesia to stimulate local and international pharmaceutical companies to enhance their research activities.

Providing tax incentives is one mechanism to attract investment in the pharmaceutical sector. Besides tax holidays, the government can offer tax reductions for expenditures related to R&D, construction of new production facilities, or technological capacity enhancements. For example, India has implemented incentive schemes that provide tax deductions of up to 150% for R&D expenses, directly contributing to the rapid growth of its pharmaceutical industry (Ivus, 2021). Furthermore, incentives such as import duty exemptions for research equipment and pharmaceutical raw materials not yet produced domestically can accelerate local capacity development. This will help reduce production costs and enhance the competitiveness of local pharmaceutical products in global markets.

International collaboration is critical in accelerating technology transfer and enhancing local capacities. Indonesia can establish strategic partnerships with advanced pharmaceutical countries such as Germany, Japan, and the United States. Through technology transfer programs, local pharmaceutical companies can access cutting-edge technologies, such as biotechnology and nanotechnology, which can be used to develop innovative pharmaceutical products (Singh, 2024). Additionally, international collaboration can be facilitated through expert training programs. The government can collaborate with global universities and research institutions to send Indonesian researchers and pharmaceutical professionals to learn about the latest technologies and best practices in the pharmaceutical field. Upon their return, these experts can contribute to enhancing local capacity in the sector.

Developing skilled and competent human resources in the pharmaceutical sector is a key element in building a sustainable innovation ecosystem. The government should support education and training programs in pharmacy and biotechnology, including scholarships for advanced studies both domestically and abroad. Additionally, intensive training for the local pharmaceutical industry workforce should focus on using advanced technologies and implementing international standards. Strengthening cooperation among universities, research institutions, and industry is also necessary to create curricula relevant to industry needs. For instance, internship programs in pharmaceutical companies can provide practical experience for students, making them more prepared to contribute to the industry upon graduation.

6. Policy Transformation to Achieve National Drug Resilience

National drug resilience is a vital component of the healthcare system, serving as a guarantee for the availability of medicines for the public (World Health Organization, 2010). However, achieving this resilience requires policy transformation that is strong in regulation and effective in implementation. This policy transformation must include strengthening regulations, optimizing implementation, fostering multi-sector collaboration, and encouraging innovation in developing local pharmaceutical products (Algorri et al., 2022). Strong and adaptive regulations are the

main foundation for achieving national drug resilience. The government must strengthen the regulatory framework by ensuring implemented policies support pharmaceutical independence. One important step is encouraging local production through policies that reduce dependency on imported active pharmaceutical ingredients (API). Law No. 17 of 2023 has provided a solid legal foundation, but its implementation requires more specific derivative regulations to ensure these policies can be effectively operationalized. Furthermore, harmonizing domestic regulations with international standards such as those of the WHO and PIC/S (Pharmaceutical Inspection Co-operation Scheme) can enhance the competitiveness of Indonesia's pharmaceutical industry in the global market. Supporting regulations must also include incentives for innovation, such as tax reductions for research and development (R&D) and streamlined licensing processes for new locally developed drugs.

One of the biggest challenges in implementing pharmaceutical policies in Indonesia is inconsistency in execution. Many well-designed regulations face implementation delays due to slow bureaucracy, lack of interagency coordination, and insufficient budget allocations (Widowati & Zamroni, 2023). Therefore, a more systematic approach is needed to ensure consistent implementation of regulations across all levels of government. To address this, the government can establish a specialized body responsible for monitoring and evaluating the implementation of national drug resilience policies. This body should have a clear mandate, adequate resources, and the authority to coordinate various stakeholders, including ministries, regulatory bodies, and the pharmaceutical industry. National drug resilience cannot be achieved without close collaboration between the government, academia, industry, and society. The government must act as a facilitator, creating a collaborative ecosystem, while academia can contribute evidence-based research to support innovation in the pharmaceutical sector. Meanwhile, the pharmaceutical industry should be encouraged to invest in the development of local products, both through financial incentives and regulatory support. International partnerships can also be a key element in accelerating policy transformation. Indonesia can establish collaborations with advanced countries for technology transfer, expert training, and capacity building in production. Successful examples from countries like India, which has leveraged international collaboration to strengthen its pharmaceutical industry, can serve as relevant models for Indonesia.

Innovation is a key pillar in creating sustainable national drug resilience. The government must encourage the development of new pharmaceutical products based on local biodiversity, such as phytopharmaceuticals and biosimilars, which have significant potential to compete in international markets. Additionally, digital technology can improve efficiency in drug distribution and supply chain tracking, ensuring that medicines are available on time across Indonesia. The government can establish a national pharmaceutical innovation center equipped with modern research facilities to support innovation. This center can serve as a hub for academia and industry to collaborate on developing new pharmaceutical products. Furthermore,

strengthening education and training in pharmacy and biotechnology should also be a priority to create a competent and innovative workforce.

National drug resilience encompasses not only the availability of medicines but also ensuring that they are accessible to all layers of society. Transparent and affordable drug pricing policies must be implemented to avoid access disparities. The government can use mechanisms such as pooled procurement to lower drug prices, particularly for essential medicines that are critically needed by the public.

7. Legal Policy Framework for National Drug Resilience

National drug resilience is not merely a healthcare strategy but also a complex legal policy framework that requires the integration of legal theory, local legal literature, and human rights dimensions. This necessitates an interdisciplinary approach combining utilitarianism and progressive legal theories as foundations for designing pharmaceutical policies that are fair, responsive, and adaptive to both global and domestic needs. In the Indonesian context, integrating these theories provides a more holistic perspective on how pharmaceutical policies can be implemented to achieve national self-reliance in drug supply.

8. Utilitarian Theory: Maximizing Benefits for Society

Utilitarian theory, as formulated by Jeremy Bentham and further developed by John Stuart Mill, emphasizes the importance of maximizing benefits for the wider society (Marseille & Kahn, 2019). In the context of pharmaceutical policy, this approach is relevant in ensuring the availability of affordable drugs for the public, especially vulnerable groups. Subsidies for essential medicines are a concrete application of this theory, where subsidies can reduce drug prices, making them accessible to individuals across various income levels. Additionally, pooled procurement offers efficiency in drug distribution and cost reduction, as practiced in countries like Brazil and India (Parmaksiz, 2023). However, the main challenge in applying utilitarianism is ensuring the sustainability of the local pharmaceutical sector. Policies overly focused on short-term benefits, such as poorly targeted subsidies, may overlook the need for long-term investments in research and development (R&D). Moreover, pressure to maintain low prices often hampers the capacity of local industries to compete, particularly in developing innovative products. Therefore, utilitarian-based policies must be balanced with incentives for local industries, such as research subsidies, tax holidays, or import duty exemptions for raw materials not yet available domestically.

9. Progressive Legal Theory: Legal Adaptation to Social and Economic Dynamics

Progressive legal theory, developed by Satjipto Rahardjo, provides a relevant perspective for addressing contemporary challenges in the national pharmaceutical system. This approach emphasizes that laws should be adaptive, flexible, and responsive to social and technological dynamics (Herlindah and Darmawan, 2022). In

the context of national drug resilience, progressive law can be applied through expedited licensing processes for generic and phytopharmaceutical drugs to ensure swift and affordable public access to essential medicines (Rahardjo, 2002). Additionally, this theory encourages policies supporting local innovation, such as establishing national pharmaceutical research centers focusing on biodiversity-based drug development. For example, Indonesia has significant potential for developing phytopharmaceutical products, but this potential remains underutilized due to complex regulations and limited research infrastructure (Badan POM, 2023).

Progressive law emphasizes the importance of creating regulations that function as supervisory tools and facilitators of innovation. However, the challenge for progressive law in Indonesia lies in navigating stringent international regulations, such as the TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement, which limits the flexibility of developing countries in using compulsory licenses for pharmaceutical products. In this regard, progressive law must be integrated with international diplomatic strategies to ensure that global regulations do not impede the development of local pharmaceutical industries. Additionally, efforts are needed to bridge global and local interests through international collaboration in technology transfer and strengthening domestic research capacity.

10. Integrating Legal Theories in National Pharmaceutical Policy

The integration of utilitarian and progressive legal theories provides a comprehensive framework for designing national drug resilience policies. Utilitarianism offers guidance on maximizing societal benefits, while progressive law provides the flexibility to respond to local and global needs. This approach can be translated into various policies, such as providing fiscal incentives for biodiversity-based research, strengthening local pharmaceutical production infrastructure, and fostering international partnerships for technology transfer.

Concrete measures include prioritizing innovation-supportive policies, such as research subsidies and tax incentives for pharmaceutical companies investing in natural product development. Furthermore, regulations that facilitate expedited licensing processes for phytopharmaceutical products can enhance the competitiveness of local products in international markets. In terms of distribution, policies emphasizing equity, such as subsidies for essential medicines, can ensure that the benefits of these policies reach all societal levels.

11. Human Rights as a Pillar of Pharmaceutical Policy

The dimension of human rights, particularly the right to health, is a crucial pillar in national pharmaceutical policy. Article 28H of the 1945 Constitution of Indonesia asserts that every citizen has the right to health services, including access to safe, effective, and affordable medicines (Riyanto, 2020). This framework is reinforced by Indonesia's commitment to the International Covenant on Economic, Social, and Cultural Rights (ICESCR), which obligates states to ensure universal access to essential medicines (Muis et al., 2023). However, the realization of this right is often

constrained by budgetary limitations and policy priorities. For instance, budget allocations for medicine subsidies often compete with other infrastructure development needs (Mahendradhata, 2021). Therefore, the government must ensure that the right to health is prioritized in national budget planning. Additionally, transparent oversight mechanisms are necessary to ensure that pharmaceutical policies genuinely benefit the broader society without discrimination.

12. Integrating Local Legal Literature and Policy Implementation

National drug resilience policies must refer to existing local legal foundations, such as Law No. 36 of 2009 on Health and Law No. 11 of 2020 on Job Creation (Fakrulloh and Lubna, 2023). Articles 101 to 103 of Law No. 36 of 2009 emphasize that citizens are entitled to safe, high-quality, and affordable medicines (Muis, 2023). However, implementing these principles faces weak interagency coordination and ineffective oversight mechanisms. On the other hand, the Job Creation Law offers significant opportunities to attract investment in the pharmaceutical sector through simplified licensing processes and fiscal incentives (Suroso, 2024). Nevertheless, this potential has not been fully realized due to a lack of mechanisms ensuring that such investments align with national needs. Therefore, local regulations must be strengthened with policies that balance economic incentives with public interests.

13. **Learning from International Practices**

Indonesia can learn from other developing countries, such as India and Brazil, which have successfully integrated utilitarian and progressive legal theories into their pharmaceutical policies. India, for instance, has utilized compulsory licensing to improve the accessibility of generic drugs without violating TRIPS provisions (Kaur and Chaturvedi, 2015). Meanwhile, Brazil has adopted pooled procurement systems, enabling the government to purchase medicines in bulk at discounted prices (Perehudoff, 2021). These countries demonstrate how pharmaceutical policies can be designed to meet societal needs while supporting the growth of local industries Guennif and Ramani, 2010).

D. CONCLUSION

Through the lens of utilitarianism and progressive legal theory, the study of national drug resilience demonstrates that pharmaceutical policies serve as both regulatory instruments and strategic tools to achieve broader social welfare. Utilitarian theory, focusing on maximizing societal benefits, provides guidance to ensure fair and affordable access to essential medicines. On the other hand, the progressive legal approach offers adaptive legal flexibility to socio-economic dynamics, fostering innovation and supporting the self-reliance of the national pharmaceutical industry. Policy transformation based on integrating these two theories has significant potential to create a self-reliant, inclusive, and sustainable pharmaceutical ecosystem. Inclusive policies should encompass strengthening local industries through fiscal incentives, technological modernization, and support for

biodiversity-based research and development. Furthermore, adaptive regulations and multi-sector collaboration must be reinforced to ensure universal access to safe, effective, and affordable medicines. This holistic approach supports national pharmaceutical self-reliance and establishes drug resilience as a critical foundation within the health law system. With these strategic measures, Indonesia can strengthen the role of law as a driver of innovation, social justice, and global competitiveness in the pharmaceutical sector. The integrated implementation of these policies will significantly contribute to public health while enhancing Indonesia's position on the international pharmaceutical industry map.

REFERENCES

1. Algorri, M., Abernathy, M. J., Cauchon, N. S., Christian, T. R., Frankenfeld Lamm, C., & Moore, C. M. V. (2022). Re-envisioning pharmaceutical manufacturing: Increasing agility for global patient access. *Journal of Pharmaceutical Sciences, 111*(3), 593–607.
2. Badan POM. (2023). *Laporan tahunan Badan Pengawas Obat dan Makanan 2023*. Jakarta: Badan Pengawas Obat dan Makanan.
3. Cane, P., & Kritzer, H. M. (Eds.). (2010). Chapter 38: Qualitative approaches to empirical legal research. In *Oxford Handbook of Empirical Legal Research* (pp. 927–950). Oxford University Press.
4. Fakrulloh, Z. A., & Lubna. (2023). Legal review of hospital responsibility for medical actions carried out by doctors. *Jurnal Indonesia Sosial Sains, 4*(12), 1237-1247.
5. Gamalliel, N., & Fuady, A. (2024). Indonesia's new health law: Lessons for democratic health governance and legislation. *The Lancet Regional Health-Southeast Asia*, 23, Article 100390.
6. Gough, I. (1978). Theories of the welfare state: A critique. *International Journal of Health Services, 8*(1), 27–40.
7. Government of India, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals. (2023, December 5). *Potential of phytopharmaceutical products in the country: Rajya Sabha starred question No. 27*.
8. Guennif, S., & Ramani, S. V. (2010). Catching up in pharmaceuticals: A comparative study of India and Brazil. *HAL Open Science*.
9. Herlindah, H., & Darmawan, Y. (2022). Development legal theory and progressive legal theory: A review in Indonesia’s contemporary legal reform. *Peradaban Journal of Law and Society, 1*(1), 14–27.
10. Hermawan, E., Hadiyati, N. A., Adiarso, A., Setiyadi, E. D., Zunuraen, S., Hidayat, D., Wahyudi, A., & Ru’yi, H. A. (2023). Challenges and policy supports in Indonesian pharmaceutical raw materials industry. *Indonesian Journal of Health Administration (Jurnal Administrasi Kesehatan Indonesia)*, 11(2), 196–211.
11. Huda, N., Adha, I. A. F., & Ashfina, S. R. S. (2020). *The role of research and development expenditure on GDP growth: Selected cases of ASEAN 5 plus 4 Asia major countries*. INDEF Working Paper No. 5/2020.

12. Huda, N., Pawennei, I., Ratri, A., & Taylor, V. L. (2020). *Making Indonesia's research and development better: Stakeholder ideas and international best practices*. Bappenas and Knowledge Sector Initiative (KSI).
13. Ivus, O., Jose, M., & Sharma, R. (2021). R&D tax credit and innovation: Evidence from private firms in India. *Research Policy, 50*(1), 104128.
14. Kaur, A., & Chaturvedi, R. (2015). Compulsory licensing of drugs and pharmaceuticals: Issues and dilemma. *Journal of Intellectual Property Rights, 20*, 279–287.
15. Lubis, R. F., Siregar, R. S., Siregar, A. F., & Mujahiddin, S. S. (2023). The industrialization of medicinal plants in Indonesia. *African Journal of Food, Agriculture, Nutrition and Development, 23*(5), 23285-23304.
16. Mahendradhata, Y., Andayani, N. L. P. E. P., & Marthias, T. (2021). COVID-19 health system response monitor: Republic of Indonesia. *WHO World Health Organization Regional Office for South-East Asia*.
17. Marseille, E., & Kahn, J. G. (2019). Utilitarianism and the ethical foundations of cost-effectiveness analysis in resource allocation for global health. *Philosophy, Ethics, and Humanities in Medicine, 14*(5).
18. Muis, L. S., Jened, R., Barizah, N., & Tjwan, G. C. (2023). State responsibility for access and availability of patented drugs for public health. *Yuridika, 38*(2), 219–242.
19. Parmaksiz, K., Bal, R., van de Bovenkamp, H., & et al. (2023). From promise to practice: A guide to developing pooled procurement mechanisms for medicines and vaccines. *Journal of Pharmaceutical Policy and Practice, 16*, 73.
20. Perehudoff, K., Mara, K., & 't Hoen, E. (2021). *What is the evidence on legal measures to improve the transparency of markets for medicines, vaccines and other health products (World Health Assembly resolution WHA72.8)?* Health Evidence Network synthesis report 73. World Health Organization.
21. Permata Bank. (2024, June). *Monthly industry report: Pharmaceutical industry*. Retrieved from: https://www.permatabank.com/sites/default/files/2024-08/Monthly%20Industry%20Report%20-%20Pharmaceutical%20Industry%20-%20Jun%202024.pdf.
22. Pradana, Y., & Arijanto, A. (2024). Implementation of strategic human resource management in improving the quality of education. *Indonesian Journal of Business Analytics, 4*(2), 483–502.
23. Rahardjo, S. (2002). *Polisi Sipil dalam Perubahan Sosial di Indonesia*. Kompas.
24. Rina, R. (2020, April 27). Harga Bahan Baku Obat Melonjak 30% di Tengah Pandemi Corona. *CNBC Indonesia*.
25. Riyanto, B. (2020). National Law Development in the New Normal Era. *Indonesian Law Journal, 13*(2), 87–107.
26. Singh, K., Nainwal, N., & Chitme, H. R. (2024). A review on recent advancements in pharmaceutical technology transfer of tablets from an Indian perspective. *Annales Pharmaceutiques Françaises*. Advance online publication. https://doi.org/10.1016/j.pharma.2024.07.003.

27. Suroso, J. T., Durahman, D., & Budi, I. (2024). The simplification of licensing procedure in job creation law: The effectiveness to attract foreign investors. *Cogent Social Sciences, 10*(1), 2414509.
28. The Prakarsa (2020). *Towards sustainable tax policies in ASEAN: A case for progressive taxation*. Retrieved from: https://repository.theprakarsa.org/media/publications/314887-towards-sustainable-tax-policies-in-asea-83d96a80.pdf.
29. Tijaja, J., & Faisal, M. (2014). *Industrial policy in Indonesia: A global value chain perspective* (ADB Economics Working Paper Series No. 411). Asian Development Bank.
30. Tjandrawinata, R. R. (2020). *Konsep Obat Modern Asli Indonesia (OMAI) dalam penggunaannya di fasilitas kesehatan formal: Working paper Mei 2020*. https://doi.org/10.6084/m9.figshare.12367331
31. Widowati, I. G. A. R., & Zamroni, M. (2023). Indonesia facing challenges of pharmaceutical care implementation in community pharmacies: A legal perspective. *Jurnal Hukum Prasada, 10*(2), 69–79.
32. World Health Organization. (2010). *Monitoring the building blocks of health systems: A handbook of indicators and their measurement strategies*. World Health Organization.