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RESEARCH ARTICLE

Exploring Challenge and Opportunities of Drug Formulation Manufactures in Indonesia's Policy Shift

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Abstract

Indonesia's pharmaceutical industry faces critical challenges due to its heavy reliance on imported Active Pharmaceutical Ingredients (APIs), which account for over 90% of total API use. This dependency creates inefficiencies, high costs, and vulnerabilities in supply chains, particularly during crises like the COVID-19 pandemic. To address this, the Indonesian government introduced the Change Source policy in 2022, aiming to enhance local production and reduce import dependency. This study explores the challenges and opportunities for drug formulation manufacturers amid this policy shift. Using a qualitative approach, data were gathered through in-depth interviews with four manufacturers and analysis of relevant regulations and secondary sources. Key challenges include high initial investment costs, inadequate infrastructure, and market demand uncertainties. However, opportunities arise from government incentives, increased local API demand, and innovation potential. Findings emphasize the importance of regulatory support, infrastructure development, and market assurance to foster sustainable growth in the pharmaceutical sector. By addressing these challenges, the policy has the potential to significantly boost Indonesia's pharmaceutical self-reliance, reduce costs, and enhance resilience. This research provides a comprehensive understanding of the policy's impacts, offering valuable insights for policymakers and stakeholders in the pharmaceutical industry.

Keyword: Active Pharmaceutical Ingredients, Supply Chain, Manufacturers, Indonesia, Policy

Introduction

The pharmaceutical industry plays a vital role in achieving national health resilience. However, Indonesia heavily relies on imported Active Pharmaceutical Ingredients (APIs), with over 90% sourced from other countries, including China, India, Europe, and the United States (Regulation of the Minister of Health No. 13 of 2022 Concerning Amendments to Regulation of the Minister of Health No. 21 of 2020 Concerning the Strategic Plan of the Ministry of Health for 2020 - 2024, 2022). Some intermediate (the basic substance to create API) are still sourced from China, India, Europe and US (Dewi Kusuma, 2016). China continues to dominate as Indonesia's primary supplier of pharmaceutical intermediates, contributing around Rp6.84 trillion or 60% of the total supply. India ranks second with Rp3.42 trillion (30%), followed by Europe, which accounts for Rp1.4 trillion (10%) (Muharti, 2012). APIs play a crucial role in the pharmaceutical supply chain as they are the most valuable and clinically essential components (Khan & Rauf, 2024)

This dependency raises concerns about inefficiency due to high costs, unpredictable lead times, and potential shortages. According to the Permata Institute for Economic Research (2024), raw material costs represent the largest share of production expenses in pharmaceutical, comprising about 79% of the total. Producing APIs domestically presents an opportunity for Indonesia to reduce costs and strengthen economic and health resilience, because the local pharmaceutical industry is predicted to be able to meet around 75% of the drug needs for the domestic market (Kartika, 2023).

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When COVID-19 pandemic happened, it exposed vulnerabilities in global supply chains (Adak, 2024), significantly impacting Indonesia's pharmaceutical industry due to its reliance on imports. Restrictions on exports and imports during the pandemic underscored the risks of dependency on foreign suppliers. As a result any disruptions in supply can significantly impact the continuity of the pharmaceutical industry, such as a drug shortage happens when there is an inadequate supply of API resulting in the unavailability of medications for patients who require a suitable alternative (Adak, 2024) and potentially affect public healthcare services (Zubair et al., 2021). Recognizing these challenges and opportunities, the Indonesian government introduced the Change Source policy in 2022, aiming to reduce import dependency and enhance the independence of local pharmaceutical industries. Local pharmaceutical production should ensure quality medicines, prevent shortages, create jobs, reduce costs, boost self-reliance, and support sustainable treatment programs (United Nations Industrial Development Organization, 2015).

Since its launch in July 2022, the change source policy has caused significant challenges and opportunities (Nurfauzia, 2024), especially for drug formulation manufacturers. Currently, Indonesia is facing several challenges, including insufficient economies of scale, a lack of investment incentives in the pharmaceutical raw materials sector, and the absence of market guarantees (Zubair et al., 2021). To help address these difficulties, regulations and incentives have been introduced to simplify implementation, ease industry burdens, and promote the use of local APIs such as tax deduction, tax holiday, standard of Domestic Component Level (DCL), and more. However, a more in-depth and comprehensive understanding of the impact of changes in source policy on drug formulation manufacturers is still needed.

This study aims to explores the challenges and opportunities faced by drug formulation manufacturers in Indonesia amidst this policy shift, by calculating the impact from regulations issued by government in support of the change source policy.

Problematic linkage used to help identify the challenges and opportunities caused by each regulation toward drug formulation manufacture. This research expected to give a hollistic understanding about the impact of change source policy to drug formulation manufacturers for policymakers and other stakeholders.

Method

This study uses qualitative research approach to explore the challenges and opportunities faced by drug formulation manufacturers under Indonesia's change source policy. Data collection method used in this research can be divided into primary and secondary sources, to ensure more comprehensive analysis as an action of triangulation. Primary data collected by conducted in-depth interviews with 4 (four) drug formulation manufacturers, that focus on understanding what challenges and opportunities that appeared as impact from government regulations. In-depth interviews are used to gather detailed insights from participants, employing open-ended questions to explore their opinions, motivations, and perspectives within a specific context (Flick, 2018). Secondary data sourced from Indonesia's regulations documents, internal reports from government agency and companies, online news, and others journal academics related to the topic of API or study case from another country that has similar policy. Thematic content analysis used to extract patterns and themes from interview response, and narrative analysis used to highlight critical insights and stakeholder experiences. The data analysis process involved familiarizing with the data, coding, categorizing, organizing by themes, and ultimately compiling the research findings.

Results and Discussion

Currently, it is understood that developing the pharmaceutical raw materials industry faces several challenges. The production process involves a complex supply chain, encompassing raw material sourcing, intermediate production, and final manufacturing. Each production phase may rely on resources and raw materials from various countries, and any disruption in one stage can result in instability in the supply of pharmaceutical ingredients (Wahyudi et al., 2023). This situation inspired efforts to strengthen resilience in the pharmaceutical and medical device sectors. The government introduced regulations on sourcing policies for intermediates and Active Pharmaceutical Ingredients (APIs) to make Indonesia's pharmaceutical industry self-reliant and globally competitive. The change source program aims to help formulation industries replace imported APIs with locally produced ones, supporting the push for self-sufficiency in APIs and domestic pharmaceutical products (Research Team of RICS API, 2024).

According to Risalah (2023) there are 217 drug formulation manufactures and 18 local API manufactures. These manufactures can be categorized into 3 (three), there are state-owned enterprise, private-domestic, and multinational companies. The supply chain of pharmaceutical industry in Indonesia start from supplier of imported raw material (intermediate) -> distributor importer of API and intermediate -> local API manufacturers -> drug formulation manufacturer -> distributor of finished drug -> health service facility & pharmacy. The pharmaceutical industry follows a set process before a drug with a changed API source is released to the market. First, local manufacturers develop the API, then the downstream team manages the API source change. A bioequivalence test is conducted at a BE testing center. After that, the API is processed and registered for a Drug Distribution Permit (DDP) by the pharmaceutical industry and the Indonesian Food and Drug Authority (IFDA). Finally, the drug formulation must meet Domestic Component Level (DCL) certification before it can be listed in the e-catalog.

In general, the change source policy in Indonesia will actually benefit drug formulation manufacturers, in terms of ease of obtaining products, more affordable prices, and other reasons. However, the impact of the regulations issued to support change source regulations is broader than that. Based on the interview results, it is known that the challenges faced by drug formulation manufacturers include:

- High initial investment cost: establishing production facilities and meeting regulatory standard, production capacity is capital expensive
- Market demand uncertainty: limited on market demand, no guarantees and competitive pricing from imports
- Limited infrastructure: lack of facilities for research, production ecosystem, and testing.
- Need more incentives beyond bioequivalency testing such as stability, formula standards, and technology transfer that burdening the management of company.
- Short validity period for Domestic Component Level (DLC) and Drug Distribution Permit (DDP), complexity of regulatory approval that takes time

Opportunities that can be leveraged by drug formulation manufacturers include:

- Government incentives: subsidy for bioequivalency (BE) test, government policy on freeze-unfreeze in e-catalog,
- Increased demand: because change source policy is promoting local API use in drug formulations
- Innovation potential: support local research and development to improve API quality and production.

According to Wahyudi et al., (2023), the development of the pharmaceutical raw materials industry can be achieved with support from four key components: government backing, a domestic market foundation, research for innovation and sustainability, and investment support. This allign with the insight explained before from the interview. To facilitate more detail for identification of the impacts, including opportunities and challenges faced by drug formualtion manufacturers due to regulations supporting the change source policy, a problematic linkage matrix is used, as shown in Table 1.

Table 1 Problematic Linkage Matrix between Regulations and Drug Formulation Manufacturers

No	Impact to Drug Formulation Manufacturers
	Presidential Instruction No. 6 of 2016 concerning Acceleration of Development of Pharmaceutical and Medical Device Industry
1.	Opportunities: Getting a stable and reliable local supply of active pharmaceutical ingredients (APIs) for ensuring consistent drug production and reducing reliance on imports. Government incentives, such as tax incentives and subsidies, can encourage investment in domestic pharmaceutical manufacturing and infrastructure. These measures, combined with a focus on fostering innovation in drug formulation, enable the development of more effective and competitive medicines. Challenges: There are often concerns about whether newly formulated drugs will succeed in the market, creating hesitancy among manufacturers. Additionally, the cost of locally produced active pharmaceutical ingredients (APIs) remains a challenge, as they are not yet competitive with imported alternatives. These factors can discourage investment and innovation in local drug production.
	Regulation of the Minister of Health No. 17 of 2017 concerning the Action Plan for Accelerating the Development of the Pharmaceutical and Medical Device Industry
2.	Opportunities: Shifting raw material sources from imported to local suppliers is a critical step in strengthening domestic pharmaceutical production. However, this transition often comes

	with significant challenges, including the high costs associated with clinical trials and regulatory registration. These expenses can place a financial burden on manufacturers, slowing the adoption of local sources.
Regulation of the Minister of Industry No. 16 of 2020 concerning Provisions and Procedures for Calculating the Value of Domestic Component Levels of Pharmaceutical Products	
3.	Opportunities: Adjusting raw materials to comply with Domestic Component Level (DCL) requirements often increases costs and extends the time needed for bioequivalence (BE) testing. Additionally, the short validity period of DCL certificates poses administrative challenges, requiring frequent renewals. These difficulties are further exacerbated by the uncompetitive pricing of locally produced active pharmaceutical ingredients (APIs)
Regulation of the Minister of Health No. 13 of 2022 concerning Amendments to Regulation of the Minister of Health No. 21 of 2020 concerning the Strategic Plan of the Ministry of Health for 2020 - 2024	
4.	Opportunities: Adapting to local raw materials is essential for reducing reliance on imports and building a resilient pharmaceutical industry. To support this transition, securing government incentives can help offset costs and encourage investment in local production. At the same time, ensuring the quality and availability of these raw materials is crucial to maintaining consistent drug manufacturing standards.
IFDA Regulation No. 11 of 2022 concerning BE Test Implementation Procedures	
5.	Opportunities: The shift to local raw materials often leads to increased operational costs, posing a challenge for manufacturers. However, this transition also opens opportunities for achieving certifications that demonstrate compliance with domestic standards.
IFDA Head Decree No. 65 of 2022 concerning the List of Certain Generic Drugs Requiring BE Testing	
6.	Opportunities: The obligation to conduct bioequivalence (BE) testing on generic products adds significant operational costs for manufacturers. Despite these additional expenses, BE testing ensures the certainty of product quality and safety, which is crucial for maintaining consumer trust. Meeting regulatory requirements for BE testing helps guarantee that generics perform similarly to their branded counterparts, providing affordable yet reliable alternatives.
Decree of the Director General of Pharmaceuticals and Medical Devices No. HK.02.02/E/523/2023 concerning the Pharmaceutical Industry Receiving the BE Change Source API Amlodipine Test Facility	
7.	Opportunities: Easing the process of changing raw material sources can help reduce the costs associated with bioequivalence (BE) testing. By streamlining this process, manufacturers can cut down on operational expenses and improve efficiency. This reduction in costs can, in turn, enhance competitiveness in the market, enabling companies to offer more affordable products without compromising quality.
Decree of the Director General of Pharmaceuticals and Medical Devices No. HK.02.02/E/571/2024 concerning the Pharmaceutical Industry Receiving the BE Change Source API Azithromycin and Bisoprolol Test Facility	
8.	Opportunities: Simplifying the process of changing raw material sources can significantly reduce the costs associated with bioequivalence (BE) testing. By lowering these costs, manufacturers can enhance the affordability and accessibility of generic products. This, in turn, increases the competitiveness of generics in the market, allowing them to better challenge branded alternatives.
Decree of the Minister of Health of the Republic of Indonesia No. HK.01.07/MENKES/1314/2023 concerning Substitution of Imported Drugs & Medical Devices with Domestic Drugs and Medical Devices in the Health Sector Electronic Catalog	
9.	Opportunities: Easing substitution policies can create more opportunities for manufacturers to introduce alternative products, especially generics, into the market. This can expand market access, particularly in government facilities that prioritize cost-effective solutions. However, these opportunities come with the challenge of improving quality standards to ensure that substituted products meet the necessary safety and efficacy requirements. Challenges: Despite regulations intended to promote local production, they remain ineffective, as healthcare facilities often prefer imported products over domestic alternatives. This preference is driven by perceptions of higher quality, not competitive in price yet, or reliability stock.
Decree of the Minister of Health of the Republic of Indonesia No.HK.01.07/MENKES/1333/2023 concerning Increasing the Use of Pharmaceutical Preparations Using Domestically Produced Raw Materials	
10.	Opportunities: Greater flexibility in raw material selection can open up more opportunities for products to be included in sectoral catalogs, facilitating easier access to markets, especially in government and institutional procurement. However, this flexibility also presents challenges in maintaining consistent quality control.
Decree of the Director General of Pharmaceuticals and Medical Devices No. HK.02.02/E/1195/2023 concerning the Pharmaceutical Industry Receiving the BE Change Source API Candesartan Test Facility	
11.	Opportunities: Obtaining permits for the substitution of raw materials can streamline the process of using local ingredients in drug production, making it more efficient and cost-effective. However, this process requires careful management to ensure the efficient use of local raw materials while meeting the necessary regulatory standards.
IFDA Regulation No. 15 of 2023 concerning the Fourth Amendment to the Head of BPOM Regulation No. 24 of 2017 concerning Criteria and Procedures for Drug Registration	
12.	Opportunities: Boosting demand for local raw materials can stimulate growth in domestic production and reduce reliance on imports. To achieve this, improving the quality and production standards of locally sourced ingredients is essential, ensuring they meet the same rigorous criteria as imported alternatives. Securing government support for local API producers through incentives, subsidies, or streamlined regulations can further encourage investment and innovation in the domestic pharmaceutical sector. Challenges: meeting new quality standards, increasing costs and time in Drug Distribution Permit (DDP) registration, short validity period of DDP
Decree of the Minister of Health of the Republic of Indonesia No. HK.01.07/MENKES/163/2024 concerning the Consolidation Showcase in the Ministry of Health's	

	Sectoral Electronic Catalog
13.	Challenges: Increased competition from locally produced raw material-based products can create challenges for manufacturers, particularly in terms of pricing. While local products may offer cost advantages, price issues often arise when consolidating products into sectoral catalogs, as manufacturers strive to balance affordability with profitability. This pricing pressure can make it difficult for local producers to remain competitive, especially when competing with imported products that may benefit from economies of scale or other advantages.

Based on findings from interviews validated by secondary data, significant challenges for drug formulation manufacturers were revealed, including high initial investment costs, infrastructure gaps, and limited market assurance. Despite these challenges, government has initiated some actions such as tax incentives and priority on procurement indicating a promising opportunity for growth, and more. Despite the Ministry of Industry's rule requiring over 52% local content in pharmaceutical products and the Ministry of Health prioritizing locally made drugs in the health sector catalog, industry experts feel these policies don't guarantee that healthcare facilities in Indonesia will choose local products. The freeze-unfreeze policy and pricing in the consolidated drug catalog need to be reviewed to support market acceptance. Local APIs are still more expensive than imports, making them less competitive and driving up drug formulation prices. Healthcare facilities can still opt for imported products instead of local ones. Therefore, continued focus on imports and pricing adjustments is needed to avoid burdening the local pharmaceutical industry.

From the regulations issued, several implications have been highlighted by drug formulation manufacturers. These include concerns about certification timelines, such as the need to extend the validity of DCL and DDP certifications to reduce administrative burdens, and simplifying regulatory compliance processes to encourage manufacturer participation. From the infrastructure and technology perspective, the industry requires increased government investment in R&D to drive innovation, as well as the development of bioequivalency testing to ensure quality standards and reduce reliance on imported APIs. Cross-collaboration among government agencies, the private sector, and universities may also be necessary to support API research and development.

Limitation Of The Study

This study focuses exclusively on Indonesia's drug formulation manufacturers, does not incorporate global comparative analyses in detail and does not explore the technical specifics of API production processes or conduct a detailed economic analysis of the supply chain.

Conclusions and Recommendations

Conclusions

The change source policy is a crucial move towards achieving pharmaceutical self-reliance in Indonesia. By encouraging the use of locally sourced active pharmaceutical ingredients (APIs), the policy aims to reduce the nation's dependency on imported raw materials, promoting long-term sustainability within the domestic pharmaceutical industry. However, drug formulation manufacturers face significant challenges in the process, particularly in terms of the high costs of initial investments in infrastructure and technology (research and development). Additionally, there are concerns about market demand, as healthcare facilities may still prefer imported products over locally produced alternatives.

Despite these obstacles, government incentives, such as subsidies, tax breaks, provide essential support for manufacturers seeking to invest in local production capabilities. Moreover, the increasing demand for affordable and reliable medicines presents a growing opportunity for innovation in drug formulations. The potential for improved market access, especially through policies prioritizing domestic products in healthcare catalogs, further strengthens the case for investing in local pharmaceutical manufacturing.

While the transition to local sourcing faces some immediate hurdles, the long-term benefits of reduced dependence on imports, coupled with government support and rising demand, create a promising environment for the growth and development of the Indonesian pharmaceutical sector. By overcoming the challenges associated with infrastructure and market acceptance, the industry can foster innovation, reduce costs, and contribute significantly to Indonesia's pharmaceutical self-reliance.

Recommendations

Recommendations can be divided into 3 (three) section:

1. Regulatory support: To ease the burden on drug formulation manufacturers, it is crucial to extend the validity of certifications such as Domestic Component Level (DCL) and Domestic Drug Product (DDP). Extending these certifications would not only help reduce the high costs associated with frequent renewals but also streamline the administrative processes involved, allowing manufacturers to focus more on production rather than paperwork. Additionally, providing more targeted incentives such as funding for stability testing, which is often a significant financial burden, would make it easier for local producers to meet regulatory requirements. Moreover, offering support for technology transfers could help foster innovation by enabling local manufacturers to adopt new technologies, improve production methods, and scale up operations more effectively. These regulatory measures would create a more supportive environment for local pharmaceutical manufacturers to thrive.
2. Infrastructure development: To strengthen Indonesia's pharmaceutical manufacturing capabilities, it is essential to enhance infrastructure, particularly in the areas of research and development (R&D) and bioequivalence (BE) testing. Expanding R&D capabilities through partnerships with universities and other research institutions would foster innovation and the development of new formulations, ensuring that local products meet international standards. By establishing collaborations with academic and research institutions, manufacturers can gain access to cutting-edge research, new technologies, and expert knowledge. Furthermore, developing specialized BE test facilities within the country would help reduce reliance on external testing centers, cut down costs, and speed up the approval process for generics. This would ensure that locally produced pharmaceuticals meet the same quality standards as their imported counterparts, improving their competitiveness in the market
3. Market assurance: To ensure the success of local pharmaceutical products in the market, the government should introduce stricter regulations on the importation of active pharmaceutical ingredients (APIs). This would help level the playing field by making it more difficult for imported products to dominate, thus creating more opportunities for locally sourced APIs to be absorbed by the market. Additionally, establishing guaranteed procurement quotas for local API drug formulations in government health facilities through the e-catalog system would provide a reliable demand for locally produced medicines. By ensuring that a certain percentage of public health procurement is dedicated to locally sourced products, the government can drive market absorption, giving local manufacturers the assurance of consistent demand. These policies would not only support the growth of the local pharmaceutical industry but also contribute to the broader goal of achieving self-reliance in pharmaceutical production.

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