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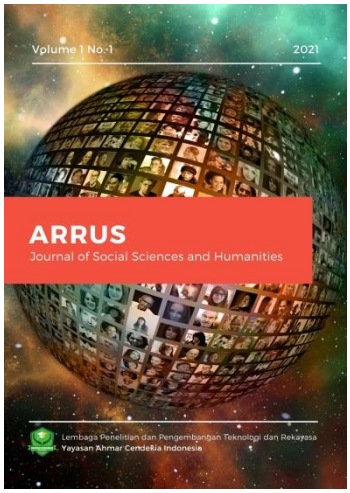

RESEARCH ARTICLE

Fiscal Policy And Tax Implications For Medical Device Resilience In Indonesia

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Abstract: The high dependence on imported medical devices in Indonesia poses challenges to national resilience in the healthcare sector. Fiscal policies, including taxation regulations, fiscal incentives, and import substitution strategies, play a significant role in enhancing the competitiveness of the domestic medical device industry. This study employs a normative method with a legislative approach to analyze the impact of taxation regulations on the competitiveness of the medical device industry. The findings indicate that: 1) Import duties regulated under PMK No. 26/PMK.010/2022 provide protection for local products but require synergy with fiscal incentives as outlined in PP No. 45 Tahun 2019; 2) Import substitution policies have successfully increased local production, yet are still constrained by dependence on imported raw materials; 3) Tax regulations, such as Article 22 of Law No. 36/2008 and the imposition of a 10% VAT, contribute to protecting the domestic market, but the tax burden on end consumers remains a challenge; and 4) A more integrated and sustainable fiscal policy framework is required to foster innovation, efficiency, and the acceleration of the independence of the medical device industry in Indonesia. This study highlights the importance of strengthening fiscal regulations to support the resilience of the national healthcare sector.

Keywords: Fiscal Policy, Medical Devices, Import Substitution, Competitiveness, Import Duties, Fiscal Incentives, Industrial Independence

1. Introduction

The healthcare industry in Indonesia continues to grow rapidly, driven by increasing demand for medical devices due to population growth, expansion of healthcare facilities, and the implementation of the National Health Insurance (JKN) program. According to data from the International Trade Administration, Indonesia's medical device market reached USD 3.586 billion in 2021, with imports accounting for 94% of total domestic needs (Nawawi et al., 2021). This reliance on imports highlights the lack of self-sufficiency in Indonesia's medical device sector, which largely focuses on basic products like surgical masks and gloves (Furqon et al., 2024).

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Fiscal policies play a crucial role in the development of the medical device industry, particularly through tax incentives and regulations that promote domestic investment. Studies show that well-planned fiscal policies can stimulate economic growth by investing in healthcare infrastructure and providing tax incentives for medical technology innovation (Norrahman, 2024). The Indonesian government, through Presidential Instruction No. 6 of 2016, also aims to accelerate the development of the pharmaceutical and medical device industries as part of efforts to achieve independence and resilience in the healthcare sector (Hadiwibowo, 2010). However, implementing fiscal policies faces challenges such as coordination gaps between agencies and a lack of regulatory harmonization. Tax court cases related to import duties on medical devices highlight regulatory barriers that may slow local industry growth (Mulyana et al., 2023). With the rising demand for medical devices, strategic fiscal policies are key to ensuring resilience and sustainability in this sector (Behera & Dash, 2018).

Furthermore, research by Hadiwibowo (2010) indicates that fiscal policies focused on development spending have a positive impact on economic growth and investment, including the healthcare sector. This includes allocating larger funds for healthcare infrastructure to improve access and service quality (Hadiwibowo, 2010). These findings align with Norrahman (2024), who states that tax incentives for the private sector can accelerate investments in healthcare technology innovation, thereby enhancing the competitiveness of Indonesia's medical device industry (Norrahman, 2024).

2. Literature Review

Based on this phenomenon, the research questions addressed in this study are as follows. First, what are the regulations governing medical device imports in Indonesia? Second, how does fiscal policy manage the balance between import duties and import substitution strategies? Third, what is the impact of tax regulations on the competitiveness of domestic medical device products? Finally, what are the implications of fiscal policy in supporting the resilience and sustainability of the national medical device industry?

3. Research Method And Materials

This study falls under the category of normative legal research, also known as doctrinal legal research. Normative legal research emphasizes the analysis of primary legal materials, such as laws, regulations, and court rulings, as well as secondary legal materials, such as relevant legal literature. The main focus of this study is to analyze the relationship between fiscal policy and the resilience of medical devices in Indonesia, considering aspects of tax regulations, import policies, and support for import substitution in the medical device sector.

Peter Mahmud Marzuki identifies several approaches in legal research, including the statute approach, case approach, historical approach, comparative approach, and conceptual approach (Marzuki, 2017). This study employs a combination of these approaches, particularly the statute and case approaches. The statute approach is used to examine relevant regulations, such as Article 23A of the 1945 Constitution, Law No. 17 of 2006 on Customs, Law No. 36 of 2008 on Income Tax, and derivative regulations like Minister of Finance Regulation No. 188/PMK.04/2020, which provides import duty facilities for specific sectors, and Presidential Instruction No. 6 of 2016, which targets the acceleration of domestic medical device development. This approach enables an in-depth analysis of the legal foundations supporting fiscal policies in the medical device sector.

The case approach is utilized to analyze court decisions related to tax disputes and import duties on medical devices. For example, rulings on the implementation of Article 22 of Law No. 36 of 2008 in determining tax obligations for imported medical devices are reviewed. This analysis aims to understand the extent to which tax regulations and fiscal policies are applied in practice and their impact on the medical device industry. Additionally, the conceptual approach is employed to examine legal concepts such as import substitution, fiscal incentives, and economic independence, as outlined in Article 33 of the 1945 Constitution

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and Government Regulation No. 45 of 2019 on Tax Incentives for Innovation-Based Industries. This approach helps to establish the theoretical framework underlying the development of fiscal policies to support the resilience of the national medical device industry.

4. Results And Discussion

4.1. Regulations on Medical Device Imports in Indonesia

Medical device imports in Indonesia are governed by various regulations aimed at ensuring the quality, safety, and efficiency of medical devices entering the domestic market. One of the main legal frameworks is Law No. 17 of 2006 on Customs, which regulates import procedures, including customs processes and import duties. Additionally, Minister of Health Regulation No. 62 of 2017 on the Distribution of Medical Devices establishes standards for distribution and registration to ensure that imported medical devices meet quality and safety criteria. This regulation aligns with Minister of Finance Regulation No. 188/PMK.04/2020, which provides government-borne import duty facilities for specific medical devices to accelerate procurement during emergencies, such as the COVID-19 pandemic (Adji, 2024; Nawawi et al., 2021).

While these regulations aim to improve accessibility to medical devices, the high dependence on imports poses challenges to the self-sufficiency of the domestic industry. Data indicate that approximately 94% of medical devices in Indonesia are imported, reflecting the limited production capacity of local industries (Francis, 2012; Nawawi et al., 2021). Regulations, such as Article 22 of Law No. 36 of 2008 on Income Tax, which governs import taxes, can be used as instruments to restrict certain imports and encourage import substitution. However, these regulations are often deemed insufficient to strengthen the domestic medical device industry without effective incentive policies, as outlined in Government Regulation No. 45 of 2019 on Tax Incentives for Innovation-Based Industries (Hadiwibowo, 2010).

The primary objective of imposing import tariffs is to protect domestic industries, control import flows, and align the prices of imported goods with those of locally produced products. In the medical device sector, import tariffs vary depending on the type and classification of the medical devices being imported. The applicable tariff rates in Indonesia are regulated under Minister of Finance Regulation (PMK) No. 26/PMK.010/2022 on the Determination of Classification Systems and the Imposition of Import Tariffs for Imported Goods (Nurfatriani et al., 2015; Rosdiana et al., 2018).

Under this regulation, there are 123 tariff categories imposed on the import of medical devices. The details of these 123 tariff categories are as follows:

Table 1: Import Tariffs and Taxes on Medical Devices

Tariff Type	Description
Import Duty 0%	15 tariff categories
Import Duty 5%	78 tariff categories
Import Duty 10%	19 tariff categories
Import Duty 15%	5 tariff categories
Import Duty 20%	4 tariff categories
Import Duty 25%	2 tariff categories
Value Added Tax (VAT)	10% (based on Article 7 paragraph 1 of Law No. 42 of 2009)
Income Tax (PPh) - with Importer ID (API)	2.5% (using Importer Identification Number)
Income Tax (PPh) - without API	7.5% (without Importer Identification Number)

4.2. Fiscal Policy on Import Duties vs Import Substitution

Fiscal policy through the implementation of import duty tariffs aims to protect domestic industries by controlling the influx of imported goods and aligning the prices of imports to be more competitive with local products. In the context of medical devices, import duty rates vary based on product type, as regulated under Minister of Finance Regulation No. 26/PMK.010/2022, with tariffs ranging from 0% to 25%. This policy provides room for

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local products to compete in the domestic market by reducing pressure from cheaper imported goods. Additionally, Article 22 of Law No. 36 of 2008 on Income Tax provides a mechanism for imposing additional taxes on imported goods, which also serves as an instrument to encourage import substitution (Anwar & Mulyadi, 2012; Halimatussadiah et al., 2022; Nawawi et al., 2021).

However, import substitution policies require strong fiscal incentives to support the development of domestic production capacity. Based on Government Regulation No. 45 of 2019 on Tax Incentives for Innovation-Based Industries, incentives such as tax holidays and tax allowances can be granted to businesses investing in the development of local products, including medical devices. Research by Hadiwibowo (2010) highlights that government spending to support import substitution can significantly enhance the competitiveness of domestic industries, particularly through investments in technology and innovation (Hadiwibowo, 2010). In the long term, import substitution policies supported by fiscal incentives can reduce dependence on imported goods while strengthening national economic resilience.

In pursuing independence and improving the competitiveness of the domestic medical device industry, the government faces a dilemma between lowering import duties and promoting import substitution policies in Indonesia. According to Law No. 17 of 2006 on Customs, import duties are state levies imposed on goods imported into Indonesia. Imports refer to the activity of bringing goods into Indonesian customs territory, which includes land, waters, airspace, and designated areas in the Exclusive Economic Zone (EEZ) and the continental shelf governed by customs laws. Reducing import tariffs has a direct impact on increasing the volume and value of imported goods and services. This policy is one of the efforts to meet the high demand for medical devices in Indonesia and to achieve national resilience. On the other hand, lowering import tariffs is considered less favorable as it may hinder the growth of the domestic medical device industry due to a surge in imported products. This policy could also increase dependence on foreign countries. Medical device manufacturers, pharmaceutical companies, and foreign medical technology firms could take advantage of market opportunities through investments or imports facilitated by this ease of access (Cottrell et al., 2017; Sparrow et al., 2017).

Another policy option to achieve medical device resilience is through import substitution strategies. Import substitution is a trade policy that promotes replacing imported goods with domestically produced products. This policy is based on the idea that a country should reduce its reliance on foreign goods and develop its domestic industry. During the 2019–2022 period, the Indonesian government, through the Ministry of Industry, implemented import substitution policies for medical devices. In this period, 152 out of 496 medical products were locally produced. However, only 12% of raw material transactions for medical devices were sourced domestically. This highlights that most raw materials for medical devices still need to be imported (Nawawi et al., 2021; Siregar & Patunru, 2021).

To support import substitution, the government must increase import tariffs to reduce the inflow of imported products and protect domestic producers. If the government focuses more on enhancing domestic production capacity, the resilience of medical devices may take longer to achieve. Using the infant industry argument, many developing countries adopt import substitution policies, where domestic industries are built under the protection of tariffs or import quotas. While this policy has succeeded in promoting the growth of domestic industries, it generally does not lead to the expected economic growth and improvement in living standards. This has led to arguments, such as those by Nawawi (2021), that import substitution policies often create high-cost and inefficient production systems (Nawawi et al., 2021).

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Table 2: Imported Medical Devices to Indonesia with Brands and Foreign Companies

Medical Device Type	Brand	Foreign Importing Companies	Description	Import Duty (%)	VAT (%)	Income Tax (PPh) (%)	Reference
CT Scan	Siemens Somatom, GE Revolution	Siemens Healthineers (Germany), General Electric (GE Healthcare, USA)	Medical imaging machine using X-rays to produce cross-sectional images of the body.	5%	10%	2.5% (API), 7.5% (non-API)	Ministry of Health (2022); PMK No. 26/PMK.010/2022
MRI (Magnetic Resonance Imaging)	Philips Ingenia, GE Signa	Philips Healthcare (Netherlands), General Electric (GE Healthcare, USA)	Medical imaging equipment using magnetic fields and radio waves to produce detailed images of body tissues.	10%	10%	2.5% (API), 7.5% (non-API)	Ministry of Health (2022); PMK No. 26/PMK.010/2022
Ventilator	Dräger Evita, Medtronic Puritan Bennett	Drägerwerk AG (Germany), Medtronic (USA)	Medical devices that help patients breathe by pumping air into the lungs.	5%	10%	2.5% (API), 7.5% (non-API)	Ministry of Health (2022); PMK No. 26/PMK.010/2022
Ultrasound Machine	GE Voluson, Philips EPIQ	General Electric (GE Healthcare, USA), Philips Healthcare (Netherlands)	Diagnostic equipment using high-frequency sound waves to produce images of internal organs.	5%	10%	2.5% (API), 7.5% (non-API)	Ministry of Health (2022); PMK No. 26/PMK.010/2022

4.3. Impact of Tax Regulations on the Competitiveness of Domestic Medical Device Products

Tax regulations, including import duties, Value Added Tax (VAT), and Income Tax (PPh), play a significant role in influencing the competitiveness of domestic medical device products. Low import duties, for example, can benefit imported products in terms of price and availability in the domestic market. According to Minister of Finance Regulation No. 26/PMK.010/2022, import duties for medical devices range from 0% to 25%, depending on the type of product. This creates challenges for local manufacturers, as they must compete with cheaper and often more innovative imported products (Nawawi et al., 2021). Research by Hadiwibowo (2010) highlights that without protective tax regulations, local industries may face significant pressure from foreign products (Hadiwibowo, 2010).

The imposition of a 10% VAT on both imported and locally produced medical devices, as stipulated in Article 7, Paragraph 1 of Law No. 42 of 2009, adds a burden to end consumers but does not directly support local producers. Conversely, if the government provides tax reductions for local manufacturers, such as tax allowances or tax holidays regulated under Government Regulation No. 45 of 2019, the competitiveness of local products could improve. Studies by Nawawi et al. (2021) show that fiscal incentives focusing on tax reductions for local industries have a positive impact on increasing production capacity and innovation(Adrison, 2024; Nawawi et al., 2021).

Additionally, different income tax (PPh) rates for imported products with or without an Importer Identification Number (API)—2.5% for products with an API and 7.5% for those without—offer incentives for companies with more structured import processes. However,

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this policy does not provide sufficient protection for local manufacturers to expand their market share. Research by Nawawi (2021) suggests that fiscal policies focused solely on import incentives tend to weaken efforts toward import substitution in the long term, leaving countries highly dependent on foreign products (Nawawi et al., 2021).

To enhance the competitiveness of local products, tax regulations should be designed to encourage domestic investment. Policies such as tax holidays and reduced import duties on raw materials can stimulate innovation and lower production costs. Research by Norrahman (2024) emphasizes the importance of harmonizing tax regulations to create an ecosystem that supports sustainable development of local industries (Norrahman, 2024). With an integrated approach, tax regulations can serve as a strategic tool to boost the competitiveness of domestic medical device products in both local and global markets.

4.4. Implications of Fiscal Policy for Supporting the Resilience of the National Medical Device Industry

Fiscal policy plays a key role in supporting the resilience of the national medical device industry, particularly through tax incentives and adequate budget allocations for the healthcare sector. One strategic measure is providing tax incentives, such as tax allowances and tax holidays, to domestic medical device manufacturers (Arnold, 2012; Syamali & Masaru, 2011). Government Regulation No. 45 of 2019 on Tax Incentives for Innovation-Based Industries provides the legal basis for granting these facilities to encourage investment in research and development of medical devices. A study by Hadiwibowo (2010) indicates that fiscal expenditures aimed at supporting import substitution can enhance national industry independence and reduce reliance on imported products (Hadiwibowo, 2010).

In addition to tax incentives, targeted budget allocations for the development of infrastructure and local production capacity are also critical factors. Presidential Instruction No. 6 of 2016 on the Acceleration of Pharmaceutical and Medical Device Industry Development emphasizes the importance of government investment in strengthening domestic industries(Dian Wahyudin & Laina, 2023; Ispriyarso & Wibawa, 2023). However, research by Nawawi et al. (2021) highlights that the implementation of this policy still faces challenges, particularly the high dependence on imported raw materials. For instance, only 12% of raw materials for medical devices can be supplied locally, underscoring the need to enhance national production capacity (Nawawi et al., 2021).

On the other hand, fiscal policy can also be used to protect the domestic market through the imposition of import duties on foreign products. Minister of Finance Regulation No. 26/PMK.010/2022 establishes import duties for medical devices ranging from 0% to 25%, providing protection for local manufacturers by limiting the entry of certain imported products. However, Nawawi (2021) cautions that tariff protection must be accompanied by improvements in efficiency and innovation by local producers to avoid stagnation caused by high-cost production (Nawawi et al., 2021).

National resilience in medical devices can also be strengthened through import substitution programs supported by fiscal policies. The government implemented this policy during the 2019–2022 period by producing 152 out of 496 medical device products locally. However, the success rate remains low due to the continued high dependence on imported raw materials. Research by Norrahman (2024) highlights that the success of import substitution requires a combination of fiscal incentives, market protection, and the strengthening of local innovation ecosystems (Norrahman, 2024). With an integrated fiscal strategy, the government can accelerate the achievement of sustainable national medical device resilience.

5. Conclusion

Tax regulations, such as Article 22 of Law No. 36 of 2008 and Minister of Finance Regulation No. 26/PMK.010/2022, protect the domestic medical device industry through the imposition of import duties. However, this policy must be complemented by incentives to enhance domestic production efficiency and reduce reliance on imports. Fiscal incentives,

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including tax allowances and tax holidays as stipulated in Government Regulation No. 45 of 2019, have a significant impact on improving the competitiveness of local products by encouraging innovation and investment in the medical device sector. Nevertheless, their implementation requires stronger support through a national innovation ecosystem. Although import substitution policies have made progress—evidenced by the local production of 152 out of 496 medical devices between 2019 and 2022—they still face major challenges due to dependence on imported raw materials, highlighting the need for more integrated and sustainable fiscal policies. To support national medical device resilience, fiscal policies must be designed comprehensively, encompassing domestic market protection, capacity-building for production, and support for innovation and efficiency, as outlined in Presidential Instruction No. 6 of 2016.

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