



Juridical Analysis of Used Medical Device Import Regulations in Indonesia

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Abstract

This study examines the legal framework governing the importation of used medical devices in Indonesia, balancing healthcare accessibility with public safety. The introduction highlights the dilemma faced by developing nations regarding cost-effective healthcare solutions versus the risks of substandard medical equipment. The methods utilize a normative legal research approach, analyzing primary and secondary legal sources, including statutory regulations and judicial frameworks. The results indicate that while Indonesian law strictly regulates the import of second-hand goods to protect public health, certain regulatory ambiguities and enforcement gaps persist, particularly regarding exceptions for essential medical technology. The discussion delves into the literature review and comparative legal structures, demonstrating a significant research gap in how specific administrative guidelines align with overarching consumer protection and healthcare laws. It analyzes the tension between economic feasibility for local healthcare providers and the constitutional right to health safety. The conclusions suggest that the current regulatory framework requires harmonization, and the study

offers concrete recommendations for legislative updates to establish clearer certification standards and stricter oversight mechanisms.

Keywords: Used Medical Devices, Import Regulation, Normative Jurisprudence, Healthcare Law, Consumer Protection.

Introduction

The intersection of public healthcare accessibility and stringent regulatory oversight presents a continuous challenge for developing nations, particularly within the framework of Indonesian jurisprudence. The importation of used medical devices serves as a pivotal focal point for this tension, as healthcare providers seek cost-effective alternatives to expensive new technology, while the state maintains a constitutional obligation to protect citizens from substandard or hazardous equipment. The formulation of the legal problem in this study centers on the potential contradictions and ambiguities within Indonesian import laws, specifically examining how current regulations under the Ministry of Trade and the Ministry of Health govern the entry of refurbished medical apparatus. The primary objective of this research is to evaluate the legal consistency, efficacy, and enforcement mechanisms of these existing frameworks to determine whether they adequately safeguard public health while remaining economically viable. The benefit of this research lies in its capacity to provide legislative recommendations for policymakers, judicial clarity for legal practitioners, and an updated compliance roadmap for healthcare administrators navigating import protocols. The central hypothesis posits that the current legal structure in Indonesia regarding second-hand medical imports lacks the necessary integration and clarity, thereby creating loopholes that could compromise patient safety and violate consumer protection standards. While previous studies have broadly addressed the restriction of used goods imports, a distinct research gap exists concerning the specific technical, legal, and bioethical criteria applied exclusively to medical equipment. The novelty of this manuscript rests on its comprehensive normative synthesis of newly enacted trade omnibus laws alongside statutory health regulations, mapping out an updated legal taxonomy for medical device accountability that has not been thoroughly synthesized in contemporary legal literature.

Methods

This study strictly employs a normative legal research method, which analyzes law as a cohesive system of rules, principles, and statutory doctrines. Rather than measuring empirical data or field behavior, this legal methodology focuses on the internal consistency and hierarchical alignment of written legal texts within the Indonesian legal hierarchy. The primary legal materials analyzed include the Indonesian Civil Code, Law Number 17 of 2023 concerning Health, and various ministerial regulations issued by the Ministry of Trade and the Ministry of Health governing the technicalities of importing capital goods in an unnew condition. Secondary legal materials comprise academic journals, authoritative legal textbooks, comparative jurisprudence literature, and official explanatory memorandums that interpret the primary statutes. The research approaches utilized include the statutory approach, which scrutinizes the literal and purposive interpretation of the legislation, and the conceptual approach, which unpacks underlying jurisprudential notions of state liability, consumer protection, and administrative law. The collected legal materials are processed through qualitative normative analysis, applying deductive logic to assess whether specific lower-level ministerial decrees conform to or contradict the higher-level constitutional mandates regarding the right to health and safety.

Results

The normative analysis reveals a fragmented legal landscape characterized by overlapping jurisdictions between Indonesian administrative bodies. Under prevailing trade regulations, the importation of used goods is generally prohibited as a protective measure for domestic industries and public safety, yet specific exceptions are granted for capital goods that are deemed non-procurable domestically or essential for national infrastructure. However, the results indicate that the specific classification of refurbished medical devices fluctuates unpredictably between these exempted categories and outright prohibitions. While the Ministry of Health mandates strict registration, certification, and calibration protocols for all medical tools to ensure clinical efficacy, the enforcement of these standards on imported used items remains legally tenuous due to the absence of a

unified cross-sectoral verification protocol. Furthermore, the analysis shows that the statutory definitions of "used," "refurbished," and "remanufactured" medical equipment are inadequately distinguished within Indonesian legislation, which leads to arbitrary administrative decisions at ports of entry and leaves local healthcare institutions exposed to legal liabilities under the Consumer Protection Act when malfunctions occur.

Discussion

The literature review on medical law establishes that the state holds a fundamental duty of care to regulate any technology directly impacting human life, a principle deeply embedded in global bioethics and Indonesian constitutional law. Scholarly consensus confirms that while the financial constraints of healthcare facilities in developing regions justify the acquisition of pre-owned equipment, the legal framework must guarantee that these devices perform identically to new counterparts. In analyzing the specific legal mechanisms in Indonesia, this study uncovers a profound disconnect between macro-level economic policies and micro-level healthcare safety standards. The literature indicates that advanced jurisdictions mitigate these risks by enforcing strict third-party liability schemes and manufacturer recertification requirements before an item can be exported or imported. In contrast, the Indonesian legal framework relies heavily on post-market surveillance, which is normatively weak because it shifts the evidentiary burden of device failure onto the patient or the local hospital. This discussion emphasizes that the lack of clear legal definitions within Indonesian decrees allows low-grade, potentially contaminated, or uncalibrated devices to be misclassified during custom clearances. By examining the principles of tort law and administrative accountability, it becomes evident that the current regulatory ambiguity undermines the legal certainty guaranteed by Article 28D of the Indonesian Constitution, as it fails to provide a predictable environment for legitimate importers while simultaneously exposing citizens to clinical risks. Therefore, the literature and current normative findings collectively demonstrate that Indonesia's regulatory approach is reactive rather than preventative, failing to align the economic allowances of trade law with the absolute safety mandates of health law.

Conclusion

This study concludes that the current Indonesian legal framework governing the importation of used medical devices suffers from regulatory fragmentation, conceptual ambiguity, and a lack of hierarchical harmony between trade and health legislations. The absence of clear statutory distinctions between hazardous second-hand waste and safely remanufactured medical technology creates legal uncertainty that compromises both healthcare accessibility and consumer safety. To resolve these issues, it is recommended that the Indonesian government enact an integrated inter-ministerial decree that synchronizes the protocols of the Ministry of Trade, the Ministry of Health, and the Directorate General of Customs and Excise. This new regulation should explicitly define the technical criteria for allowable refurbished imports, mandate mandatory manufacturer recertification, and establish an independent legal authority responsible for the pre-shipment verification and continuous calibration oversight of all pre-owned medical technologies entering the country.

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