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ADMINISTRATIVE DECISIONS IN THE PHARMACEUTICAL SECTOR: A COMPARATIVE ANALYSIS OF INDONESIA AND THE UNITED STATES

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Abstrak

Keputusan administratif dalam industri farmasi memengaruhi keseimbangan antara perlindungan inovasi dan aksesibilitas obat, terutama di negara berkembang seperti Indonesia. Studi ini mengevaluasi dampak keputusan administratif terhadap sektor farmasi Indonesia dengan membandingkannya dengan kebijakan Badan Pengawas Obat dan Makanan Amerika Serikat (FDA). Studi ini menggunakan pendekatan deskriptif-kualitatif, menganalisis teori hukum administrasi, teori keseimbangan hukum Gustav Radbruch, kekayaan intelektual, dan realisme hukum. Temuan studi mengungkapkan bahwa keputusan administratif sering kali memperkuat perlindungan paten, yang mendorong inovasi tetapi membatasi akses obat, terutama bagi populasi berpenghasilan rendah. Di Indonesia, Badan Pengawas Obat dan Makanan (BPOM) menghadapi tantangan dalam memenuhi kebutuhan publik di tengah terbatasnya regulasi yang adaptif. Kendala dalam penerapan lisensi wajib dan tekanan internasional mempersulit regulasi distribusi obat, terutama dalam situasi darurat. Studi ini merekomendasikan harmonisasi regulasi dengan standar internasional, peningkatan transparansi dalam pengambilan keputusan, dan penerapan lisensi wajib untuk mengatasi ketegangan antara perlindungan paten dan aksesibilitas. Pendekatan ini diharapkan dapat menciptakan kerangka regulasi farmasi yang lebih inklusif, adil, dan responsif yang memenuhi kebutuhan publik tanpa mengorbankan inovasi.

Kata Kunci: kebijakan kesehatan publik, regulasi farmasi, kerangka hukum, dan lisensi wajib, harga obat, kebijakan akses ke obat-obatan esensial, pemerataan perawatan kesehatan

Abstract

Administrative decisions in the pharmaceutical industry influence the balance between innovation protection and drug accessibility, particularly in developing countries like Indonesia. This study evaluates the impact of administrative decisions on Indonesia's pharmaceutical sector by comparing them with the policies of the United States Food and Drug Administration (FDA). The research employs a descriptive-qualitative approach, analyzing administrative law theory, Gustav Radbruch's balance of law theory, intellectual property, and legal realism. The findings reveal that administrative decisions often reinforce patent protection, which promotes innovation but limits drug access, especially for low-income populations. In Indonesia, the National Agency of Drug and Food Control (BPOM) faces challenges in meeting public needs amidst limited adaptive regulations. Barriers to implementing compulsory licensing and international pressures complicate drug distribution arrangements, particularly in emergency situations. This study recommends harmonizing regulations with international standards, enhancing transparency in decision-making, and implementing compulsory licensing to address the tension between patent protection and accessibility. This approach is expected to create a more inclusive, equitable, and responsive pharmaceutical regulatory framework that meets societal needs without compromising innovation

Keywords: public health policy, pharmaceutical regulation, legal frameworks, and compulsory licensing, drug pricing, policies access to essential medicines, healthcare equity

INTRODUCTION

Administrative decisions in the pharmaceutical sector often lie at the center of legal and public policy dilemmas, particularly when balancing the need to protect innovation with ensuring affordable drug accessibility for the public. Pharmaceutical innovation

protection through intellectual property regulations, such as patent rights, is designed to provide financial incentives for the research and development of new pharmaceutical products. However, this mechanism can also create barriers to drug accessibility, especially in countries with limited economic resources (Kapczynski, 2019). This tension is particularly evident in the United States, where the Food and Drug Administration (FDA) holds authority to remove pharmaceutical products from the drug shortage list, a measure often implemented to strengthen patent protection. However, such measures frequently exacerbate disparities in drug access, particularly for low-income populations who rely on more affordable alternatives such as generic or compounded drugs (Kesselheim et al., 2016).

The impact of these administrative decisions extends to major pharmaceutical manufacturers operating under patent protection, compounding pharmacies, local distributors, and healthcare providers, who are forced to seek higher-cost alternatives. The system's inability to provide affordable drug access to all societal strata has become a major focus of global health studies. For example, (Outterson et al., 2022) observed that administrative decisions prioritizing patent protection often sacrifice the principle of social justice, particularly in fragmented pharmaceutical markets. Globally, this issue is not confined to developed countries like the United States. Developing nations, including Indonesia, face similar challenges but with greater complexity. Indonesia, as a country with a developing pharmaceutical system, faces significant hurdles in ensuring adequate drug availability, particularly during emergencies such as the COVID-19 pandemic. The regulatory framework managed by the National Agency of Drug and Food Control (BPOM) plays a central role in governing drug distribution. However, regulations on managing drug shortages or emergency procurement could be further developed (Organization, 2021). For instance, during the pandemic, reliance on imported products and limitations in implementing compulsory licensing were major obstacles for local production of essential drugs and vaccines (Erlangga et al., 2023).

In addition to domestic challenges, Indonesia also faces global pressures to align its regulations with international standards, such as those set by the World Trade Organization (WTO) through the TRIPS Agreement (Sulistianingsih & Ilyasa, 2022). On one hand, this agreement provides flexibility for developing countries to implement compulsory licensing in emergency situations. However, the implementation of such policies often encounters resistance from international pharmaceutical companies that strictly protect their patent rights (Kesselheim et al., 2016). This tension further complicates BPOM's ability to effectively perform its regulatory functions. This article aims to examine the impact of administrative decisions on Indonesia's pharmaceutical sector by drawing lessons from the United States' experience. The analysis connects administrative law theory, Gustav Radbruch's theory of the balance of law, and intellectual property theory to provide a comprehensive framework for developing more inclusive and equitable pharmaceutical regulations. By highlighting the practical implications of administrative decisions in both countries, this article offers solutions to enhance transparency, accountability, and the effectiveness of pharmaceutical regulation in Indonesia.

RESEARCH METHODS

This study employs a descriptive-qualitative approach, focusing on literature review and legal analysis. This method was chosen for its flexibility in exploring various theoretical perspectives and relevant regulatory practices. Descriptive analysis details the U.S. Food and Drug Administration (FDA) policies regarding removing pharmaceutical products from the drug shortage list. In contrast, legal analysis evaluates the implications of these regulations in the Indonesian context. This approach aims to integrate administrative law theory, the balance of law, and intellectual property into a relevant analytical framework to address the research questions. The

literature review includes secondary data sources, such as FDA policy documents, BPOM regulations and guidelines, intellectual property laws, and academic journals discussing the legal implications of administrative decisions in the pharmaceutical sector. The study also utilizes industry reports and case study analyses to highlight how administrative decisions affect pharmaceutical industry players and public drug access. The descriptive-qualitative approach emphasizes in-depth secondary data analysis to understand the impact of administrative decisions on the pharmaceutical sector. Secondary data includes official documents, regulations, academic journals, industry reports, and relevant case studies. The analysis process involves several stages to ensure the validity and relevance of the findings in addressing the research questions.

A. Stage 1: Secondary Data Collection

The study begins by identifying key policy documents from the FDA in the United States, such as the Hatch-Waxman Act and amendments to the Food and Drug Administration Safety and Innovation Act (FDASIA). These documents are analyzed to understand policies related to removing pharmaceutical products from the drug shortage list and their impact on drug accessibility. In Indonesia, the regulations reviewed include guidelines and rules from BPOM, such as the implementation of compulsory licensing under Law No. 13 of 2016 on Patents and policies for managing drug shortages during the COVID-19 pandemic. Secondary data also includes academic journals offering critical perspectives on the legal and social implications of these policies.

B. Stage 2: Content Analysis

The collected documents and data sources are thematically analyzed to identify patterns, trends, and challenges in the implementation of administrative decisions. For instance, analysis of FDA regulations focuses on how these policies affect the availability of generic and alternative drugs in the market and their impact on pharmaceutical industry players, compounding pharmacies, and the public. In Indonesia, the focus is on obstacles to implementing policies such as compulsory licensing and the influence of international pressures on BPOM's regulatory capabilities. During this stage, administrative law theory is used to evaluate transparency and accountability principles in administrative decision-making, while Gustav Radbruch's balance of law theory assesses the extent to which these policies fulfill the values of justice, legal certainty, and utility.

C. Stage 3: Data Triangulation

To ensure the validity of findings, the study employs data triangulation by comparing information from various sources, such as industry reports, case studies, and academic articles. For example, reports from the IQVIA Institute for Human Data Science on price increases of new drugs under patent protection are compared with data from academic journals discussing the social implications of FDA administrative decisions. In Indonesia, drug pricing data during the pandemic reported by the Ministry of Health is compared with findings from local journal research to identify disparities in drug accessibility across regions.

D. Stage 4: International Comparison

The study compares policies and best practices from the United States with the legal and regulatory context in Indonesia. The goal is to identify elements that can be adapted to Indonesia's legal system to strengthen pharmaceutical regulation. For example, the Hatch-Waxman Act, designed to expedite generic drug approvals, is analyzed as a potential model for Indonesia, with adjustments to the local context.

E. Stage 5: Policy Recommendations

Based on the analysis, the study integrates findings from various sources to provide relevant recommendations. This process involves a critical evaluation of existing regulations and potential reforms, such as more effective implementation of compulsory licensing, increased transparency in administrative decision-making, and the development of local production capacities to reduce reliance on imports. This approach ensures that secondary data analysis not only provides in-depth insights into the impact of administrative decisions but also supports the development of evidence-based policy frameworks. The systematic and verified process ensures that the findings of this study can be used to discuss and refine administrative policies in the pharmaceutical sector, both nationally and internationally. The strength of this method lies in its ability to integrate various perspectives and produce evidence-based policy recommendations. The study draws on reliable sources and seeks to validate data through triangulation of information from policy documents, academic journals, and industry reports. By employing this methodology, the research not only descriptively outlines the impact of administrative decisions but also evaluates the relevance of legal theories to construct a more inclusive and equitable pharmaceutical regulatory framework. This provides a solid foundation for discussing how administrative policies can be improved to enhance their effectiveness and efficiency, both at the national and international levels.

RESULTS AND DISCUSSION

A. Results

This research demonstrates that administrative decisions, such as the removal of pharmaceutical products from the drug shortage list, create tension among pharmaceutical industry players, regulatory bodies, and the public. The impact of these decisions can be seen from various perspectives, including economic effects, logistical challenges, and social inequities in both the United States and Indonesia. Comprehensive quantitative data and concrete case studies from both countries provide an in-depth understanding of the issues faced.

In the United States, strengthened patent protection through administrative decisions often leads to rising drug prices. Data from the IQVIA Institute for Human Data Science (2022) shows that the average price of new drugs under patent protection increased by 10.4% per year between 2016 and 2021. This impact is particularly felt in essential drugs like insulin, whose price rose from $100 per vial in 2012 to $300 per vial in 2020. The situation is exacerbated by the FDA's decisions to remove certain pharmaceutical products from the drug shortage list, often affecting compounding pharmacies. For instance, strict FDA regulations on compounded generic drugs in 2018 led to approximately 30% of compounding pharmacies in the United States reporting a revenue decline of more than 15%. This not only affected the viability of these pharmacies but also reduced drug accessibility for low-income patients, as reported by (Outterson et al., 2022).

A real-world case in the United States highlighting the impact of administrative decisions is the methotrexate shortage in 2019. Methotrexate, widely used to treat certain cancers, became difficult to access after being removed from the drug shortage list. The American Cancer Society reported that approximately 60% of patients requiring methotrexate had to switch to alternatives that were three times more expensive (Bedoui et al., 2019). This sharp financial burden worsened conditions for patients already facing an average annual cancer treatment cost of $150,000 (Smith et al., 2019).

In Indonesia, the impact of administrative decisions in the pharmaceutical sector reflects a different complexity, particularly due to the country's reliance on imported pharmaceutical raw materials (Hermawan et al., 2023). According to data from the Ministry of Health, approximately 85% of Indonesia's pharmaceutical raw materials are

imported, primarily from China and India (Mahendradhata et al., 2017). During the COVID-19 pandemic, limited access to imported raw materials hindered local production of essential drugs like oseltamivir. Drug prices increased by up to 200% in some regions, making certain medications increasingly unaffordable for the general public (Santoso, 2022).

Administrative decisions also play a crucial role in managing compulsory licensing in Indonesia. In 2020, the Indonesian government issued compulsory licenses for favipiravir and remdesivir, two essential drugs during the pandemic (Rohaini & Dwiatin, 2022). However, implementing this policy faced significant challenges, including resistance from international pharmaceutical companies protecting their patents. As a result, only about 20% of domestic demand for favipiravir was met that year (Organization, 2021).

The COVID-19 vaccine shortage in 2021 is a case study in Indonesia that illustrates regulatory challenges in the pharmaceutical sector. Dependence on imported vaccines like AstraZeneca and Sinovac, both under international patent protection, limited Indonesia's ability to produce vaccines locally. The government attempted to implement compulsory licensing to accelerate vaccine distribution, but lengthy negotiations with patent holders delayed the process. However, as of December 31, 2021, vaccination coverage had reached 79.4% for the first dose and 54.68% for the second dose (Kementrian Kesehatan RI, 2022). This exceeded the WHO target of 40% of the population being fully vaccinated by the end of 2021. The social impact of administrative decisions in the pharmaceutical sector is also significant in both the United States and Indonesia. In the United States, research by (Kesselheim et al., 2016) revealed that 25% of patients needing patented medications chose not to fill their prescriptions due to high costs. A similar situation occurred in Indonesia, where a report by the University of Indonesia's Demographic Institute (2022) noted that 40% of rural households were unable to afford essential medications during the pandemic due to a lack of affordable generic alternatives (UNICEF et al., 2022).

Based on this analysis, it is evident that administrative decisions that strengthen patent protection must be balanced with policies prioritizing drug accessibility. In the United States, policies like the Hatch-Waxman Act are designed to accelerate the approval of generic drugs, though their implementation still faces challenges. Meanwhile, Indonesia has the flexibility to leverage provisions in the TRIPS Agreement to enhance local drug production through compulsory licensing. However, this requires stronger domestic manufacturing capacity and reduced reliance on imported pharmaceutical raw materials. The findings of this study indicate that administrative decisions in the pharmaceutical sector can create tension between innovation protection and social justice. With a more inclusive and transparent regulatory approach, both countries can address these challenges and ensure equitable drug access for all segments of society

B. Discussion

1. Administrative Law Theory Approach

Administrative law theory emphasizes the importance of administrative bodies in implementing technical and specific policies in accordance with their legal mandate. In the context of the U.S. Food and Drug Administration (FDA), this theory explains that administrative agencies have the authority to interpret regulations in situations requiring flexibility. For example, the FDA's decision to remove pharmaceutical products from the drug shortage list illustrates how an administrative body exercises its authority to ensure drug distribution complies with patent protection rules. The FDA's 2018 decision to tighten regulations on generic drugs led to approximately 30% of compounding pharmacies in the U.S. reporting revenue declines of more than 15% (Hickey, 2024), directly impacting drug accessibility for low-income groups. However,

administrative law theory also demands adherence to the principles of transparency, accountability, and fair procedures (Harlow, 2006). A lack of transparency in administrative decisions often triggers resistance from industry players and the public. A relevant example is the FDA's 2019 decision to remove methotrexate from the drug shortage list, resulting in a threefold price increase and burdening cancer patients who had previously relied on the generic version of the drug (Vogler & Fischer, 2020).

In Indonesia, the National Agency of Drug and Food Control (BPOM) plays a similar role as the administrative body regulating drug distribution. However, existing regulations are often unclear, especially in emergencies or drug shortages. For instance, during the COVID-19 pandemic, the limited availability of imported pharmaceutical raw materials hindered the production of essential drugs like oseltamivir, causing prices to rise by up to 200% in some regions of Indonesia (Kementrian Kesehatan RI, 2022). By applying the principles of administrative law theory, BPOM could enhance the legitimacy of its decisions by engaging stakeholders, including industry players and the public, in public consultation processes. This would lead to more inclusive and accountable decision-making.

2. Gustav Radbruch's Balance of Law Theory

Gustav Radbruch's theory offers three primary elements of law: justice, legal certainty, and utility. In the context of administrative decisions in the pharmaceutical sector, these three elements often conflict (Alexy, 2021). For example, the FDA's decision to remove pharmaceutical products from the drug shortage list aims to maintain legal certainty by protecting intellectual property rights. However, this decision also creates injustice for patients needing access to those drugs. The increase in the price of insulin in the U.S. from $100 per vial in 2012 to $300 per vial in 2020 (IQVIA Institute for Human Data Science, 2022) highlights the disparity in access caused by patent protection.

Radbruch argues that justice should take precedence in law, especially when conflicts arise with legal certainty or utility (Leawoods, 2000). In this case, the removal of methotrexate from the drug shortage list can be seen as a violation of the principle of justice, as it restricts access to necessary medications. Conversely, public utility is also compromised as patients are forced to seek more expensive or less effective alternatives. Applying Radbruch's theory in Indonesia could guide administrative decisions toward a balance that prioritizes justice without entirely sacrificing legal certainty or utility. For example, BPOM's implementation of compulsory licensing during the COVID-19 pandemic demonstrates a step toward balancing public utility with patent protection. However, addressing global resistance and ensuring the efficient implementation of such policies requires a stronger emphasis on justice to ensure equitable access to essential drugs for all societal groups. In Indonesia, the National Agency of Drug and Food Control (BPOM) faces a similar dilemma in balancing the public's need for drug access with the protection of pharmaceutical innovation. During the COVID-19 pandemic, the implementation of compulsory licensing for favipiravir encountered resistance from international pharmaceutical companies, resulting in only 20% of domestic demand being met in 2020 (Baker & Thrasher, 2023). Radbruch's principle of the balance of law can serve as a guide for BPOM to prioritize justice and utility in emergency situations, such as drug shortages.

3. Intellectual Property Theory and Pharmaceutical Regulation

Intellectual property rights play a significant role in promoting pharmaceutical innovation by providing incentives for drug manufacturers to conduct research and development. However, this theory also highlights the potential conflict between the exclusive rights granted to patent holders and the public's need for affordable access to medicines.

In the case of the FDA, removing pharmaceutical products from the drug shortage list is based on protecting the patent rights of producers. This decision indicates that the intellectual property legal system often prioritizes commercial interests over societal needs. For example, (Kesselheim et al., 2016) reported that 25% of patients in the U.S. could not fill prescriptions for patented drugs because the prices were too high. Indonesia, as a member of the WTO, has the flexibility to implement compulsory licensing in emergencies in accordance with the TRIPS agreement. However, implementing this policy still faces various obstacles, including resistance from industry players and a lack of clear regulation mechanisms. During the COVID-19 pandemic, limitations on AstraZeneca and Sinovac vaccines protected by international patents hindered mass vaccination efforts in Indonesia, resulting in only 60% of the population being vaccinated by the end of 2021 (Kementrian Kesehatan RI, 2022).

4. Legal Realism Theory

Legal realism emphasizes legal decisions' practical effects and real-world consequences, rather than focusing solely on abstract legal principles or statutes (Angelosanto, 2023). This theory views law as a dynamic tool that should adapt to societal needs and changing circumstances (Bodansky, 2015). In the context of pharmaceutical regulation, legal realism provides a lens to evaluate how administrative decisions impact public health, industry players, and equitable access to medicines.

In the United States, the FDA's decisions, such as removing certain pharmaceutical products from the drug shortage list, demonstrate how legal realism manifests in practice. These decisions, while rooted in regulatory frameworks, often prioritize protecting patent rights to incentivize innovation. However, their real-world consequences include rising drug prices and restricted access to essential medicines. For instance, the price increase of insulin from $100 per vial in 2012 to $300 per vial in 2020 (IQVIA Institute for Human Data Science, 2022) disproportionately affected low-income populations, highlighting a gap between legal intentions and social outcomes. In Indonesia, legal realism underscores the need for regulatory bodies like BPOM to respond flexibly to public health emergencies. During the COVID-19 pandemic, Indonesia's reliance on imported pharmaceutical raw materials and patented vaccines exposed vulnerabilities in its regulatory system. The limited availability of AstraZeneca and Sinovac vaccines, coupled with protracted negotiations with patent holders, delayed mass vaccination efforts. These challenges illustrate how rigid adherence to patent protections can conflict with the urgent need to protect public health.

Legal realism advocates for a balanced approach that considers both the economic realities of the pharmaceutical industry and the societal imperative for accessible healthcare. For Indonesia, this means leveraging TRIPS flexibilities, such as compulsory licensing, while addressing systemic barriers like manufacturing capacity and regulatory clarity. Adopting a realist perspective can help align legal frameworks with the practical needs of the population, ensuring that laws serve as tools for justice and utility in the dynamic landscape of public health and pharmaceutical innovation.

5. Application of Legal Theories in the Indonesian Context

The discussion of administrative law, balance of law, intellectual property, and legal realism theories provides a comprehensive framework for analyzing administrative decisions in the pharmaceutical sector. In the Indonesian context, applying these theories can help strengthen BPOM regulations and ensure that public needs for access to medicines are met without compromising innovation protection. Administrative law theory highlights the importance of transparency and accountability in decision-making. By adopting these principles, BPOM can enhance public trust in its policies and reduce potential legal conflicts. The balance of law theory guides for BPOM to balance justice, legal certainty, and utility in pharmaceutical regulation. In emergencies, justice

and utility should be the primary priorities. Intellectual property theory provides a legal basis for the government to protect patent rights while ensuring accessibility to medicines. By implementing compulsory licensing in emergencies, BPOM can address barriers posed by the exclusive rights of pharmaceutical producers. Legal realism theory complements this framework by emphasizing the importance of pragmatic approaches in administrative decision-making.

Intellectual property rights play an equally significant role in this context. According to intellectual property law theory, patent rights incentivize innovation but also create barriers to medicine accessibility, especially in developing countries. As a member of the World Trade Organization (WTO), Indonesia is bound by the TRIPS Agreement, which provides flexibility to implement compulsory drug production licensing in emergencies. However, implementing this policy in Indonesia still faces various challenges, including resistance from industry players and a lack of clear regulatory mechanisms.

Harmonizing pharmaceutical regulations with international standards is an important step in addressing these challenges. The experience of the United States can serve as a lesson for Indonesia in improving transparency and accountability in administrative decision-making. However, such harmonization must also consider local needs and domestic capacity to efficiently produce and distribute medicines. Transparency and accountability are key elements that must be strengthened in administrative decision-making in the pharmaceutical sector. In Indonesia, BPOM must ensure that every decision is based on an open and inclusive process. This includes providing opportunities for the public and industry players to submit objections or input before decisions are made. Transparency not only enhances the legitimacy of administrative decisions but also helps reduce potential legal conflicts that could harm all parties.

6. Policy Implications

Administrative decisions in the pharmaceutical sector play a crucial role in regulating the distribution and production of drugs. However, their impact often creates tensions between protecting innovation and meeting the need for drug accessibility. This tension becomes increasingly complex in developing countries like Indonesia, where reliance on imported raw materials and domestic regulatory challenges complicate the management of the pharmaceutical sector. This article explores the economic and social impacts of administrative decisions by highlighting cases in the United States and Indonesia. Additionally, several policy recommendations are proposed to create a more inclusive and equitable pharmaceutical regulatory system.

The impact of administrative decisions also affects public trust in regulatory bodies. The lack of transparency in decision-making processes often creates perceptions of injustice. In Indonesia, BPOM has been criticized for insufficiently involving stakeholders, such as patient advocacy groups and local pharmaceutical manufacturers, in policymaking. This has led to resistance to several policies perceived as benefiting only large pharmaceutical companies (Pharmaceutical Research and Manufacturers of America, 2022). This situation underscores the importance of strengthening transparency and accountability within the pharmaceutical regulatory system.

To address these challenges, several policy measures can be implemented. In Indonesia, diversifying the supply sources of pharmaceutical raw materials should be a priority to reduce dependence on imports. The government can provide tax incentives and investments to support the development of local production facilities, increasing the manufacturing capacity for generic drugs (Tjandrawinata, 2024). Fair pricing policies, such as cross-subsidies, can be implemented to ensure vulnerable groups have

access to essential drugs. This model allows revenue from branded drugs to fund the production of more affordable generic drugs.

Additionally, the implementation of compulsory licensing in emergency situations must be optimized. The government needs to expedite negotiations with international patent holders and strengthen the legal framework to support this policy. Successful examples of compulsory licensing policies can be seen in countries that managed to locally produce essential drugs and vaccines during the pandemic (Kapczynski, 2019). Regional cooperation with ASEAN countries can also strengthen drug and raw material supply networks, reducing dependence on volatile global markets (Ministry of Health, 2021). To enhance the legitimacy and effectiveness of policies, BPOM needs to improve transparency mechanisms in decision-making. Public consultation processes involving patient advocacy groups, academics, and local pharmaceutical industries can help reduce resistance and ensure policies reflect societal needs. This approach can also increase public trust in regulatory bodies and create a more inclusive regulatory system.

Administrative decisions in the pharmaceutical sector have complex economic and social impacts. In the United States, patent protection policies often raise drug prices and limit accessibility, while in Indonesia, reliance on imported raw materials exacerbates inequalities in healthcare access. Indonesia can establish a more equitable pharmaceutical regulatory system by implementing more inclusive policies, such as local production diversification, compulsory licensing, and regional cooperation. These measures will not only improve drug accessibility but also ensure that innovation protection aligns with societal needs.

CONCLUSION

Administrative decisions in the pharmaceutical sector, such as removing a product from the drug shortage list, reflect the complexity of balancing public interests with innovation protection. In the Indonesian context, BPOM faces similar challenges in ensuring equitable drug access while safeguarding intellectual property rights. By learning from international experiences, Indonesia can strengthen its pharmaceutical regulations by applying administrative law, balance of law, and intellectual property theories. Measures such as harmonization with international standards, implementing compulsory licensing in emergencies, and enhanced decision-making transparency can help create a more equitable and responsive regulatory system. In this way, Indonesia can ensure that the public's need for affordable medicines is met without compromising the pharmaceutical innovation necessary for advancing the health sector.

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