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Regulation and Pharmaceutical Corporate Responsibility: Generic Drug Distribution, Patent Rights, and Their Impact on Equity of Access in the National Health Insurance System

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ABSTRACT

The pharmaceutical industry operates at the intersection of intellectual property rights and public health imperatives, creating a fundamental tension between drug innovation and access. This literature study examines the legal framework of corporate responsibility for pharmaceutical companies in distributing branded versus generic drugs in Indonesia, focusing on implications for access, consumer rights, and equity within the National Health Insurance (JKN) system. The analysis reveals that Indonesian law, encompassing patent, health, consumer protection, and competition regulations, establishes a normative foundation that balances exclusive rights with public interest tools like compulsory licensing. However, the strategic use of patent thickets, product hopping, and biased marketing by originator companies can undermine generic drug availability, affordability, and perception, thereby restricting consumer choice and burdening the JKN system. The study concludes that while the legal architecture is conceptually robust, its operationalization is fragmented. Effective realization of access equity requires integrated enforcement, proactive market oversight, and regulatory reforms that explicitly link corporate conduct to the sustainability of the public health insurance system. Strengthening transparency in pricing negotiations, limiting patent evergreening, and empowering the insurance authority are critical steps forward.

INTRODUCTION

The global pharmaceutical industry operates within a framework characterized by tensions between innovation incentives and access to medicines. Intellectual property rights, particularly patents, grant pharmaceutical companies a period of monopoly over branded (originator) drugs. This period is intended to compensate for the substantial investments in research and development, which Henry Grabowski (2002) identifies as a primary driver of therapeutic advancement. However, patent regimes create high prices that often limit the availability of medicines for low- and middle-income populations. This system gives rise to two categories of drugs that are legally and economically distinct: patented branded drugs and generic drugs. Generic drugs contain the same active ingredients as their branded counterparts, are produced after patent expiration, and are typically sold at significantly lower prices (Kariyawasam & Ariyaratne, 2020). The existence of these two categories shapes the landscape of healthcare access, where the availability and affordability of medicines are determined by the interaction of patent law, pharmaceutical regulation, and public health policy. The debate over the appropriate balance between innovation incentives and universal access to essential medicines has become a central issue in global health policy for decades.

In Indonesia, the legal framework governing drug distribution is rooted in Law Number 36 of 2009 on Health and Law Number 28 of 2014 concerning Copyrights, Patents, and Trademarks (as revised). These regulations seek to balance intellectual property protection with the constitutional mandate to provide equitable healthcare services. The legal rights of persons with disabilities in accessing healthcare services demonstrate that clear and accessible information is a crucial element of an inclusive health system (Subiakso et al., 2023). The

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Health Law mandates that essential medicines must be available and affordable, a principle aligned with the global commitment to health as a human right. In practice, this effort is implemented through the National Health Insurance Program (JKN) managed by Badan Penyelenggara Jaminan Sosial Kesehatan. This program relies on a drug formulary that includes many generic medicines to control costs. However, the availability of generic drugs in the market does not depend solely on health regulations but also on pharmaceutical industry practices and market structures. Pharmaceutical companies holding patents have certain legal obligations, while generic manufacturers operate under a different regulatory regime. The interaction between these two actors within the existing legal framework greatly determines the reality of medicine access at the community level (Verawaty et al., 2022).

The primary point of friction arises during the transition phase from branded drugs to generic drugs. When the patent of a branded drug expires, theoretically the market opens to generic competition that will reduce prices. However, patent holders often employ legal and commercial strategies to extend their de facto monopoly. Practices such as evergreening (obtaining new patents for minor modifications of existing drugs), patent litigation that delays generic marketing authorization, and settlement agreements that postpone the entry of generics into the market have been widely documented. These practices challenge the principle of fair competition and may delay the economic benefits of expired patents for healthcare systems and consumers. From the perspective of corporate liability law, the question arises as to the extent to which patent-holding pharmaceutical companies have obligations, beyond compliance with patent law, to facilitate a smooth transition to the generic era in order to support broader healthcare access goals (Zuardin & Ratodi, 2018). This responsibility touches upon aspects of business ethics and sustainable corporate governance.

On the other hand, the generic drug industry also bears significant legal responsibilities. Generic manufacturers must ensure that their products meet the bioequivalence and quality standards established by Badan Pengawas Obat dan Makanan (BPOM). These obligations are regulated under BPOM regulations and the Health Law. Studies on the falsification of health certificates from the perspective of criminal law and professional ethics demonstrate that patient protection requires strict law enforcement against various forms of violations (Hartika et al., 2023). Responsibility for the safety and efficacy of pharmaceutical products remains with the manufacturer, whether it is a generic company or a patent holder (Alex et al., 2023). However, market dynamics and promotional policies can influence the choices available to healthcare professionals and patients. For instance, aggressive marketing practices by branded pharmaceutical companies, or certain incentives within the distribution chain, may discredit generic drugs despite their clinical equivalence. This raises questions about corporate obligations to provide accurate and balanced information to consumers and healthcare professionals, as well as their role in supporting education on the rational use of generic medicines. Thus, issues of access and equity lie not only in pricing but also in information, perceptions, and trust shaped through industry practices.

Therefore, analysing corporate liability law related to the distribution of generic versus branded medicines requires a multidisciplinary approach. This study must investigate the intersection between health law, consumer protection law, competition law, and the principles of corporate social responsibility (CSR). Challenges and changes in national health development from legal, healthcare access, and infectious disease management perspectives require serious attention from all stakeholders (Harianto et al., 2024). Within the Indonesian legal system, Law Number 8 of 1999 on Consumer Protection and Law Number 5 of 1999 concerning the Prohibition of Monopolistic Practices and Unfair Business Competition provide relevant legal instruments. These instruments can be used to evaluate business practices that may hinder access to more affordable generic medicines or limit consumer choice. This literature study aims to map the relevant legal framework, analyse its potential and limitations, and examine how the concept of corporate liability can be interpreted and enforced to promote equitable access within Indonesia's healthcare system, without undermining the incentives necessary for future pharmaceutical innovation.

The fundamental problem lies in the potential conflict between the monopoly rights granted by patent law and the state's obligation to fulfil the right to health. Pharmaceutical companies that hold patents have exclusive rights to produce and market new medicines, which often results in high prices to cover research costs and generate profits. These high prices can place essential medicines beyond the reach of many patients and burden public health systems. Although patent law recognizes exceptions such as compulsory licensing or parallel importation to address public health concerns, these mechanisms

are rarely used in Indonesia and face complex political and legal challenges. Pharmaceutical companies may maximize their patent rights, which is legally permissible, but such actions may produce detrimental consequences from a public health perspective (Mayana & Santika, 2022). Ethical and legal questions arise regarding whether the corporate responsibility of pharmaceutical companies includes actively considering the impact of their pricing and distribution policies on access, particularly for life-saving medicines. The concept of voluntary corporate social responsibility is often insufficient to resolve this structural tension.

Another issue relates to business competition practices that may hinder the penetration of generic drugs into the market (Jatemin & Irawati, 2021). After a patent expires, competition from generic medicines should significantly reduce prices. However, former patent holders may use various tactics to maintain their market share. These tactics include marketing campaigns that promote branded medicines as superior without strong scientific evidence, providing financial incentives to pharmacies or healthcare professionals to continue prescribing branded versions, or flooding the market with derivative formulations that remain under patent protection. Such practices may violate competition law if they are proven to unreasonably restrict competition. However, proving these violations is complex and requires strong institutional capacity from competition authorities. In addition, the complex pharmaceutical supply chain, involving distributors, agents, and pharmacies, can create price distortions and non-transparent incentives. This situation may harm consumers by limiting access to cheaper and equally effective medicines, while also imposing higher costs on the National Health Insurance system than necessary.

There are also issues concerning information and consumer rights. Patients, as the final consumers of healthcare services, are often in a position of information asymmetry. They rely heavily on prescriptions and advice from healthcare professionals. The quality of healthcare services and patient satisfaction in public health services demonstrate that comprehensive and integrated information significantly influences public trust (Khayru & Issalillah, 2022). If the information received by healthcare professionals about generic medicines is biased due to certain marketing practices, or if misconceptions about the quality of generics persist, the consumer's right to obtain informed and fair choices may be compromised. Consumer protection law guarantees the right to accurate, clear, and honest information. However, its implementation in relation to pharmaceutical products, which are technical in nature and prescribed by third parties (physicians), becomes highly complex. The responsibility to provide accurate information is distributed among pharmaceutical companies (through promotional materials and labelling), healthcare professionals, and pharmacies. The absence of effective mechanisms to ensure balanced information and protect consumers from misleading claims may result in suboptimal treatment choices and unnecessary healthcare expenditures.

The increasing burden of non-communicable diseases in Indonesia, such as diabetes, hypertension, and cardiovascular diseases, requires long-term pharmacological therapy (Puspitasari et al., 2015). The cost of treatment for these chronic diseases represents a major component of expenditures for the national health insurance system. The widespread and appropriate use of generic medicines is therefore an important strategy to maintain the financial sustainability of the national health insurance program. Consequently, understanding the legal barriers and corporate behaviours that hinder the optimal use of generics has direct implications for the sustainability of the national healthcare system. This study can provide a roadmap to identify areas where regulatory intervention or law enforcement is necessary to create an environment more supportive of healthy generic competition. Thus, this issue is closely related to the state's fiscal stability and the government's ability to fulfil its constitutional commitment to provide comprehensive healthcare services.

Reforms in the health sector and Indonesia's efforts to achieve pharmaceutical self-sufficiency further reinforce the importance of this topic. The government is encouraging the development of the domestic pharmaceutical industry, which largely focuses on the production of generic medicines (Husada & Tjandrawinata, 2016). Promoting a fair ecosystem for domestic generic manufacturers is not only a matter of industrial economics but also a matter of national health resilience. Studies on the corporate responsibility of multinational and local pharmaceutical companies can reveal practices that may hinder the growth of a competitive domestic generic industry. Such understanding is important for formulating effective health industry policies and ensuring that competition regulations are implemented fairly to protect both consumers and legitimate domestic producers. In the current geopolitical climate, where the resilience of

healthcare supply chains has become a priority, equitable access and pharmaceutical self-sufficiency represent two sides of the same coin.

Globally, the discourse on access to medicines has shifted from merely a human rights issue to a complex matter of global economic governance. International trade agreements and diplomatic pressures often influence a country's policies on generic medicines. The intention to purchase environmentally friendly and medical products is influenced by green consumer behaviour, environmental concern, and recycling behaviour (Fachrurazi et al., 2022). By understanding the legal boundaries of national corporate responsibility, Indonesia can strengthen its policy position in international negotiations and design robust domestic regulations that remain consistent with international obligations. In-depth academic studies provide an evidence-based foundation for such policy debates. By exploring how existing laws can be utilized or need to be reformed to hold corporations accountable for the impact of their practices on access to medicines, this research contributes to broader efforts to create a more ethical and equitable governance framework for the pharmaceutical industry, ultimately serving the interests of public health more effectively.

This study aims to analyse the legal framework governing pharmaceutical corporate responsibility related to the distribution of branded and generic medicines in Indonesia. It also evaluates the implications of corporate commercial strategies on the generic drug market and consumer rights. Furthermore, the research examines how the principle of equitable access can be integrated into the interpretation and enforcement of corporate liability law to support the objectives of the National Health Insurance system. Theoretically, this study is expected to enrich the discourse in health and business law by providing an integrative analysis of the interaction between patent law, competition law, and consumer rights in the pharmaceutical sector. Practically, the findings of this research may provide insights for regulators, health policymakers, and civil society advocates in designing and enforcing regulations that promote a competitive, transparent, and equitable pharmaceutical market for the entire population.

RESEARCH METHOD

This research constitutes a qualitative literature study designed to develop a comprehensive analytical understanding of the legal dimensions of pharmaceutical corporate responsibility within the drug distribution ecosystem. A qualitative approach was selected due to the nature of the research problem, which requires an in-depth exploration of meanings, interpretations, and interactions among various legal norms rather than the measurement of quantitative variables. As explained by Creswell (2009), qualitative research enables scholars to develop complex themes through intensive examination of textual data.

The data used in this study are entirely secondary sources and are categorized into two main groups. The first category consists of primary legal documents, including Indonesian legislation such as the Health Law, Patent Law, Consumer Protection Law, and Competition Law, as well as derivative regulations issued by Badan Pengawas Obat dan Makanan and the Ministry of Health of the Republic of Indonesia. The second category comprises secondary academic literature, including legal textbooks, reputable national and international scientific journal articles, policy reports from organizations such as the World Health Organization (WHO), and critical analyses from credible think tanks focusing on health rights and access to medicines.

The collected data were analysed using thematic content analysis and normative legal analysis. Thematic content analysis, as outlined by Virginia Braun and Victoria Clarke (2006), was used to identify, organize, and report patterns of meaning emerging from the secondary academic literature. The process involved repeated reading of the materials, generating initial codes for key concepts such as "information obligations," "evergreening strategies," "barriers to competition," and "equitable access," and grouping these codes into coherent themes aligned with the research questions.

Meanwhile, normative legal analysis was applied specifically to the primary legal materials. This technique involved interpreting regulatory texts, examining the hierarchical relationships among legal norms, and identifying potential gaps or ambiguities within the regulatory framework. These two analytical techniques were subsequently synthesized to construct arguments addressing the research questions. The validity of the analysis was maintained through data source triangulation, which involved comparing and confirming findings across different types of literature (positive law, academic studies, and policy reports) and across multiple disciplinary perspectives (law, public health, and business ethics). This process ensures that the conclusions drawn are based on robust evidence and critical interpretation

RESULT AND DISCUSSION

Analysis of the Legal Framework of Pharmaceutical Corporate Responsibility in the Distribution of Branded and Generic Medicines in Indonesia

The discussion of pharmaceutical corporate responsibility must begin with the patent regime as the foundation for protecting innovation. The patent legal framework in Indonesia, currently regulated under Law Number 13 of 2016 on Patents, serves as the primary entry point for understanding the obligations of innovator pharmaceutical companies. This law grants exclusive rights to patent holders to exploit their inventions for a certain period of time. These rights are translated into a monopoly over the production and marketing of branded medicines. However, this legal construction is intrinsically limited by considerations of public interest. Legal protection for patients from medical negligence constitutes a fundamental aspect that must be guaranteed in every healthcare system, including in ensuring access to safe and affordable medicines (Lethy et al., 2023).

Article 109 of the Patent Law explicitly regulates compulsory licensing, a mechanism through which the government may grant permission to another party to implement a patent without the consent of the patent holder, in exchange for reasonable royalties. The grounds for granting compulsory licenses include situations where the implementation of the patent does not meet domestic needs or involves unfair practices. This provision demonstrates that patent rights are not an ultimate objective but rather an instrument subject to broader social goals, including the fulfilment of domestic pharmaceutical needs (Mayana & Santika, 2022). The corporate responsibility of patent holders, therefore, is already embedded within this law as an obligation to utilize their patents in a manner that is not arbitrary and that considers their impact on medicine availability. Failure to fulfil this implicit obligation may trigger state intervention through the use of compulsory licensing mechanisms. Thus, patent law places public interest as a normative boundary on commercial exclusivity.

Beyond the patent regime, the obligations of pharmaceutical corporations are also shaped by health law grounded in human rights principles. Law Number 36 of 2009 on Health introduces a broader, rights-based perspective. This law recognizes health as a fundamental human right and an investment in national development. Article 1 of Law Number 36 of 2009 defines health efforts as every activity and/or series of integrated, coordinated, and sustainable activities aimed at maintaining and improving public health through disease prevention, health promotion, treatment, and recovery carried out by the government and/or the community (Razy & Ariani, 2022).

Within this framework, every party involved in the implementation of healthcare efforts, including pharmaceutical corporations, has an obligation to support the realization of optimal health standards. Article 5 states that every person has the right to obtain healthcare services that are safe, of good quality, and affordable. This provision is not directed solely at the state but also creates a legal environment in which pharmaceutical business actors must operate. The distribution of medicines, both branded and generic, must therefore be placed within the framework of supporting this right. The Health Law also mandates the government to ensure the availability of essential medicines. This mandate is realized through policies such as the National Essential Medicines List and the National Health Insurance Program (JKN) managed by Badan Penyelenggara Jaminan Sosial Kesehatan. The program relies heavily on generic medicines to control healthcare costs. Consequently, pharmaceutical corporate responsibility must be understood within this policy reality: business success, particularly for branded medicines, cannot be separated from contributions to a national healthcare ecosystem that prioritizes affordability through the use of generic medicines. This responsibility is contextual and directed by public health policy. From this perspective, the commercial activities of pharmaceutical corporations are closely tied to the fulfilment of the public's right to health (Lesmana et al., 2022).

The relationship between pharmaceutical corporations and end consumers is regulated through legal instruments oriented toward individual protection. In the domain of consumer relations, Law Number 8 of 1999 on Consumer Protection establishes a set of specific obligations for business actors, including pharmaceutical companies. The core obligation is to provide accurate, clear, and honest information regarding the condition and guarantees of goods. In the pharmaceutical context, this information includes indications, contraindications, side effects, composition, and the marketing authorization number issued by Badan Pengawas Obat dan Makanan (BPOM). Regulations on medical product advertising and the protection of patients as consumers of healthcare services also require attention within a broader legal framework (Sahidu et al., 2023).

These obligations apply equally to both branded and generic medicines. The difference lies in the informational content related to patent rights and their validity period, which may be relevant for branded medicines. Crucially, the Consumer Protection Law prohibits misleading statements and standard clauses that disadvantage consumers. Marketing practices that implicitly or explicitly discredit generic medicines, or that create unfounded perceptions of superiority for branded medicines without strong scientific evidence, may potentially violate these provisions. Corporate responsibility in this context is both procedural and substantive: pharmaceutical companies must ensure that all circulating information whether through advertising, brochures, or interactions conducted by medical representatives is accurate, balanced, and not misleading. Patient satisfaction with healthcare service quality in community health centres also indicates that transparency and clarity of information significantly influence public trust (Darmawan et al., 2022). Violations may result in civil lawsuits by consumers or administrative sanctions imposed by consumer dispute settlement bodies. With these provisions, transparency of information becomes a central element in both the ethical and legal dimensions of pharmaceutical marketing.

The aspect of business competition also constitutes an important dimension in assessing the behaviour of pharmaceutical corporations (Haryanto & Iswanto, 2020). Oversight of market power and anti-competitive conduct is regulated under Law Number 5 of 1999 concerning the Prohibition of Monopolistic Practices and Unfair Business Competition. This law is highly relevant in analysing pharmaceutical corporate responsibility, particularly during the post-patent phase. Article 25 prohibits business actors from preventing, obstructing, or hindering consumers from obtaining competing goods. Tactics such as entering into agreements with distributors to boycott certain generic products, or implementing predatory pricing against new generic medicines entering the market, may fall within this category. Furthermore, Article 19 concerning monopolistic practices prohibits the abuse of a dominant position. A patent-holding pharmaceutical company that holds a dominant position within a particular therapeutic market and then uses that position to unreasonably restrict production or engage in discriminatory pricing may be subject to this provision. Corporate responsibility within the framework of antimonopoly law requires companies to conduct their business activities in a manner that supports fair competition. For patent-holding companies, this means reasonably accepting the entry of generic competitors once patent protection expires, without designing strategies aimed solely at artificially extending monopoly power and contradicting the spirit of competition. In this context, acceptance of post-patent competition becomes an indicator of compliance with fair market principles.

These normative provisions are reinforced by technical regulations governing pharmaceutical product standards. Technical regulations issued by Badan Pengawas Obat dan Makanan, particularly regulations concerning generic medicines, add another layer of highly specific obligations. These regulations establish standards for quality, safety, and efficacy that must be fulfilled by all medicines, including strict bioequivalence requirements for generic drugs. Consumer protection in the healthcare sector, including the legal responsibility of pharmacists, also requires strict governmental oversight (Setiawan et al., 2023). The primary obligation of pharmaceutical corporations producing generic medicines is to ensure full compliance with these standards. However, this responsibility may also extend to the original patent holders. In some regulatory systems, patent holders are required to provide access to reference materials or certain data necessary for the generic registration process. Although Indonesian regulations do not explicitly regulate this matter, the legal principle of good faith may still be applied. More importantly, practices such as patent evergreening the filing of new patents for minor modifications in order to extend protection may be interpreted as attempts to hinder generic manufacturers from fulfilling registration requirements by creating a complex web of patent claims. In this context, the corporate responsibility not to misuse the patent system becomes particularly crucial. Thus, technical compliance and legal ethics are closely interconnected in the distribution of generic medicines.

The entire legal regime does not operate independently but rather interacts in practice. The interaction among these various legal frameworks creates a complex mosaic of corporate responsibilities (Widjaja, 2021). A patent-holding pharmaceutical company simultaneously bears several obligations: the duty to utilize patents responsibly (Patent Law), the obligation to support an affordable healthcare system (Health Law), the duty to provide truthful information (Consumer Protection Law), and the obligation not to prevent fair competition (Antimonopoly Law). These obligations do not always operate in harmony. For

instance, the exclusive rights granted by patents may conflict with the principle of fair competition.

Strategic patent registrations can influence dynamic competition by hindering innovation from both originator companies and generic manufacturers. Moreover, such practices may directly contribute to higher medicine prices (Gurgula, 2020). These conflicts are addressed by legal mechanisms through exceptions and limitations, such as compulsory licensing and the temporal limits of patent protection. Consequently, corporate responsibility lies in the ability of pharmaceutical companies to navigate this legal space by seeking a point of balance, where incentives for innovation are respected without sacrificing public access to medicines and the principles of a fair market. Balance therefore becomes the key concept in assessing the legitimacy of pharmaceutical business practices.

The effectiveness of legal norms is also largely determined by the institutional capacity responsible for their implementation. At the level of implementation, the effectiveness of this legal framework depends heavily on the capacity and coordination of enforcement institutions. The Ministry of Health, the Badan Pengawas Obat dan Makanan (BPOM), the Komisi Pengawas Persaingan Usaha (KPPU), and the courts each possess authority based on different legislative mandates. Consumer protection and the legal responsibility of business actors in selling medicines above the maximum retail price in pharmacies illustrate the importance of price supervision in the pharmaceutical industry (Baktiasih & Mardikaningsih, 2024). A business practice that obstructs generic medicines for example, misleading information campaigns may be examined from the perspective of the Consumer Protection Law by the Badan Perlindungan Konsumen Nasional (BPKN), and from the perspective of unfair competition practices by the KPPU. The absence of strong coordination among these institutions may lead either to overlapping enforcement or, conversely, to regulatory gaps. Therefore, part of corporate responsibility lies in ensuring compliance that goes beyond merely adhering to a single law in isolation. Pharmaceutical corporations must design distribution, pricing, and marketing policies capable of withstanding scrutiny from multiple legal perspectives. Under such circumstances, corporate compliance requires a holistic and anticipatory legal approach.

Beyond the obligations imposed by positive law, social expectations toward corporations also shape behavioural standards. The aspect of corporate social responsibility (CSR), as mandated in Law Number 40 of 2007 concerning Limited Liability Companies, adds another dimension to corporate obligations. Article 74 requires companies whose activities involve or relate to natural resources to implement CSR programs. Although the pharmaceutical industry is not automatically categorized within this sector, many major pharmaceutical companies have adopted CSR initiatives related to healthcare access. Legal guarantees for children's rights in the fields of education and health also form an important component of broader societal protection (Hariani et al., 2021). Within the context of generic medicine distribution, CSR programs may take the form of public and healthcare professional education regarding the safety and efficacy of generic medicines, or medicine assistance programs for vulnerable communities. Although CSR initiatives may be voluntary to a certain extent, the existence of this legal mandate creates a social expectation that pharmaceutical corporations have responsibilities beyond purely commercial transactions. These responsibilities include active efforts to improve healthcare access, which align with promoting the rational use of generic medicines. In this context, CSR functions as a complementary mechanism to legal norms in expanding access to medicines.

All these regulations illustrate a regulatory pattern that is dispersed yet complementary. Overall, Indonesia's national legal framework does not regulate pharmaceutical corporate responsibility in the distribution of branded and generic medicines through a single comprehensive law. Instead, such responsibility is constructed in a layered and fragmented manner through the interaction of several legal regimes that embody different philosophical foundations (Magrath, 2016). The patent regime grants rights under certain conditions; the health regime establishes social objectives; the consumer protection regime safeguards individuals from asymmetric information; and the antimonopoly regime ensures fairness in market processes. The essence of pharmaceutical corporate responsibility lies in operating at the intersection of these regimes in a harmonious manner. Pharmaceutical companies must respect patent rights without abusing them, support healthcare policies without hindering innovation, provide accurate information without undermining perceptions of more affordable alternatives, and compete vigorously while remaining fair. Failure to fulfil these multidimensional responsibilities not only risks legal sanctions but may also be regarded as a failure to perform the corporation's social role within the

national healthcare ecosystem. Therefore, assessing the compliance and performance of a pharmaceutical corporation cannot be limited to a single legal dimension. Instead, it requires an integrative evaluation of how the company navigates the entire complex regulatory landscape in order to contribute to the ultimate objective: improving public access to medicines that are safe, effective, and affordable. Through such an integrative assessment, pharmaceutical corporate responsibility can be understood comprehensively within the broader framework of national health development.

Commercial Strategies, Consumer Rights, and Their Impact on the Generic Drug Market

In modern pharmaceutical industry practice, intellectual property protection strategies are often designed far beyond the sole objective of protecting innovation. The commercial strategy of patent-holding pharmaceutical companies frequently begins with the construction of dense patent portfolios known as patent thickets. This tactic involves filing a series of additional patents that protect various aspects of a drug product, ranging from crystal forms, salts, and formulations to methods of use (Karjoko et al., 2020). Although patent law requires novelty and inventive steps, in practice these secondary patents often protect incremental modifications. The direct implication for the availability of generic medicines is the delay in the registration process. Before producing generic drugs, manufacturers must conduct a freedom-to-operate (FTO) analysis to ensure that they do not infringe any active patents still in force. This complex patent maze increases legal costs and risks for generic manufacturers, which can ultimately delay or even discourage their plans to enter the market. Such delays extend the *de facto* monopoly period of patent-holding companies, even though the core patent of the drug may have already expired. From a legal perspective, this practice tests the boundary between legitimate patent exploitation and the misuse of the patent system for anti-competitive purposes. Indonesian Patent Law does not specifically prohibit patent thickets, allowing this gap to be used as a legally permissible commercial strategy, yet one with broad consequences for the availability of more affordable alternatives. This condition illustrates how the design of patent protection can function as a significant barrier.

Patent-holding companies also rely on product life-cycle management strategies to maintain their market position. One commonly used approach is product hopping, or product switching. When the core patent is nearing expiration, the company launches a new version of the same drug, for example in an extended-release formulation or a fixed-dose combination, and then aggressively promotes this new version to doctors and consumers. At the same time, the company may withdraw the older version from the market or reduce its supply. The legal rights of patients, including those with limited financial capacity, must receive protection in every health service provided (Noor et al., 2023). The implications for affordability are substantial. Generic drugs are typically developed based on older versions whose patents have expired. If the older version is no longer available in the market, generic manufacturers lose the reference product required for bioequivalence testing, which is a prerequisite for registration with the Indonesian Food and Drug Authority (Badan POM). Even if generics for the older version successfully reach the market, demand for them may already have been eroded by marketing campaigns for the newer, still-patented, and more expensive version. This strategy effectively shifts market demand from products that are about to face generic competition to products still protected by monopoly rights, thereby maintaining high prices and reducing affordable options for consumers. From the perspective of competition law, such practices may be examined to determine whether they constitute an abuse of dominant market position by artificially redirecting demand to prevent the entry of competitors. In this way, product innovation no longer functions solely for clinical purposes but also becomes a strategic instrument for managing market structure.

Another important dimension of patent-holder strategies concerns pricing policies. Pricing strategies also have profound implications. Patent-holding companies may implement differential pricing, setting different prices for different market segments. In Indonesia, they may offer special prices for government procurement through the National Health Insurance (JKN) e-catalogue system, while maintaining significantly higher prices in the commercial market or private pharmacies. Although this strategy may improve access through public channels, it can also create market distortions. Private pharmacies and hospitals may be reluctant to supply branded medicines because the profit margin is lower than the e-catalogue price, or conversely, they may only provide the more expensive versions due to incentives from distributors (Satibi et al., 2022). As a result, affordability becomes highly dependent on the purchasing channel. Patients who are not covered by JKN or who purchase medicines

through private pharmacies may face significantly higher prices. The Maximum Retail Price (HET) regulation issued by the Ministry of Health seeks to address this issue; however, determining HET for patented medicines that remain under exclusivity often involves complex negotiations and does not always reflect reasonable production costs. The implication is the emergence of unequal access based on economic capacity and distribution channels. This phenomenon demonstrates how pricing policies can interact with health financing systems to produce socially uneven consequences.

Beyond structural and economic aspects, the formation of market perception becomes a highly decisive strategic arena. Marketing and promotional practices constitute a critical area that shapes perceptions of generic medicines. Patent-holding companies invest substantial resources in medical education activities, seminars, and visits by medical representatives. These promotional materials may subtly construct a narrative about the superiority of branded medicines by emphasizing quality consistency, patient support services, or additional data derived from post-marketing studies. While such information may be accurate, disproportionate emphasis can create unfounded doubts about generic medicines in the minds of doctors and patients. Intensive promotional activities by pharmaceutical companies have been identified as a significant factor influencing prescribing preferences, sometimes at the expense of cost-effectiveness considerations (Spurling et al., 2010).

The narratives constructed in these promotional activities often utilize cognitive heuristics, whereby information presented repeatedly and in professional formats can unconsciously influence perceptions of reliability and quality (Mintzes, 2012). In an environment where physicians have limited time to evaluate every scientific claim, reliance on information sources from the industry may inadvertently lead to less rational prescribing practices. Patients, who receive this information indirectly through physicians' prescriptions, subsequently lose the opportunity to consider generic alternatives that are clinically equivalent. This situation illustrates a form of information market failure, where knowledge asymmetry is exacerbated by targeted and well-funded communication strategies. Doubts about generic medicines cultivated in this way are not merely perceptual but may have tangible public health consequences by reducing the utilization of affordable medicines and hindering the objectives of health cost-containment policies (Kesselheim et al., 2013).

Consumer Protection Law requires that information be honest and clear. However, in the context of promotion directed toward healthcare professionals which is complex and technical the boundary between scientific education and commercially biased persuasion often becomes blurred. At the same time, pharmaceutical companies are heavily restricted in their ability to communicate directly with consumers (Haider, 2023). Patients, as the final consumers, receive such information indirectly through physicians' prescriptions. If physicians' perceptions of generic medicines are influenced by unbalanced promotional strategies, then consumers' rights to obtain informed choices free from commercial bias are effectively compromised. The Indonesian Food and Drug Authority (Badan POM) regulate drug promotion; however, monitoring every interaction between medical representatives and physicians poses significant operational challenges. In this context, promotion can no longer be considered normatively neutral, as it may shape clinical preferences with systemic consequences.

The implications of these various strategies become even more evident when linked to consumers' right to choose. The relationship between these strategies and the consumer right to choice is particularly clear in the context of generic substitution. The right to choose presupposes the availability of alternatives that are accessible, affordable, and perceived as equivalent. Patent thicket and product hopping strategies limit the availability of alternatives. Differential pricing strategies affect the affordability of alternatives across different distribution channels. Marketing strategies influence the perception of equivalence. Together, these three factors can effectively constrain consumer choice, even though generic medicines may technically have been registered with the Indonesian Food and Drug Authority (Badan POM).

Patient satisfaction based on service quality and the location of healthcare facilities indicates that accessibility and service quality play a crucial role in shaping public trust (Mardikaningsih, 2022). In consumer protection law, meaningful choice requires more than the mere physical presence of a product; it requires an environment in which consumers can make rational decisions based on adequate information and without unreasonable barriers. Commercial practices that systematically create such barriers may therefore be considered contrary to the spirit of Consumer Protection Law, particularly the

principle of good faith in business conduct. Limitations on choice can occur implicitly through complex market design.

At the downstream level, distribution mechanisms play a crucial role in determining how consumer choice is ultimately realized. The role of the distribution chain and the incentives embedded within it further exacerbate these implications. Patent-holding companies often offer rebate schemes, bonuses, or loyalty programs to major distributors and pharmacies. These schemes may be tied to sales targets for branded medicines. As a result, pharmacies have financial incentives to promote the sale of branded drugs rather than generic medicines, even when physicians write prescriptions using generic names. This practice, commonly known as a brand substitution incentive, directly intervenes in consumer choice at the final point of sale. Consumers who may not fully understand the difference between branded and generic medicines can be directed by pharmacists to purchase the more expensive variant. Such practices have the potential to violate Consumer Protection Law because they exploit information asymmetry and the position of trust held by pharmacists. Moreover, if these practices are implemented widely and in a coordinated manner by patent holders, they may be examined as prohibited vertical agreements under Competition Law because their purpose or effect is to restrict competition. This condition demonstrates that the final point of sale becomes a crucial arena for the protection of consumer rights (Satibi et al., 2022).

Beyond market instruments, litigation mechanisms are also used as part of competition risk management strategies. Aggressive patent litigation strategies represent a legal instrument used to create uncertainty and delay the entry of generic medicines. Patent-holding companies may file lawsuits against generic manufacturers for patent infringement, even when the claims are weak. The primary objective is often not to win the lawsuit but to obtain an injunction or temporary order that halts the production or distribution of generics during legal proceedings that may last for years. Protection of patient rights from the perspective of legal and medical ethics in Indonesia indicates that ethical violations can have legal consequences (Herisasono et al., 2023). High legal costs and operational risks often discourage generic manufacturers particularly medium-scale producers from entering the market. The implications for availability and affordability are clearly negative. Indonesia's civil procedural framework provides mechanisms for lawsuits and provisional measures, but it does not yet contain specific provisions preventing the abuse of patent litigation as an anti-competitive tool (sham litigation). Protection for generic manufacturers from such tactics remains limited, placing them in a vulnerable position when facing large global pharmaceutical corporations. In this context, litigation functions as a non-market barrier with significant impact.

Viewed as a whole, these various strategies reinforce one another. The cumulative implication of these strategies is the creation of an unbalanced market ecosystem. This ecosystem tends to maintain the dominance of branded medicines even after patent expiration, through a combination of legal, economic, and perceptual barriers. Consumers' right to choice is effectively reduced to choosing between purchasing expensive branded medicines or facing difficulties obtaining generic alternatives due to limited availability, negative perceptions, or persuasion at pharmacies. Equity in access which forms the spirit of Health Law becomes threatened when market mechanisms function to sustain inequality through strategies that are technically legal but contrary to public health objectives. Protection of patient rights from the perspective of legal and medical ethics in Indonesia also shows that ethical violations can result in legal sanctions (Herisasono et al., 2023). This situation reflects a fundamental tension between market logic and public health mandates.

In facing such conditions, legal responses play a central role. Legal responses to these implications must not be partial. An integrated approach is required, involving coordination among the Indonesian Food and Drug Authority (Badan POM) as the product regulator, the Ministry of Health as the access policy maker, the Business Competition Supervisory Commission (KPPU) as the guardian of competitive markets, and the courts as interpreters of patent and consumer law. Analysis of electronic medical records from a health law perspective shows that proper documentation is essential to protect the rights of both patients and healthcare professionals (Kholis et al., 2023). For example, the Indonesian Food and Drug Authority could tighten requirements for secondary patents to ensure that only inventions that are truly novel and inventive receive protection. KPPU could proactively investigate practices such as product hopping or exclusive distributor incentive schemes as potential violations of competition law. Courts could develop jurisprudence rejecting speculative patent claims and imposing sanctions on parties engaging in

litigation in bad faith. Without coordination and strong enforcement, the existing legal framework will remain merely a set of rules that sophisticated commercial strategies can easily circumvent. Cross-institutional cooperation therefore becomes essential to ensure that regulatory objectives are effectively achieved.

The issue of generic medicines should be viewed within an interconnected legal and market system. The commercial and legal strategies of patent-holding companies affect not only drug prices but also market competition and the information needed to protect consumer rights. Therefore, policy debates should extend beyond pricing to include strengthening regulatory oversight, reforming patent procedures to prevent abuse, enforcing competition law more firmly, and improving public health literacy. The regulation of telemedicine in Indonesia also illustrates the importance of adaptive regulation in protecting patients in the digital era (Sasmita et al., 2023). A comprehensive approach is necessary to build an ecosystem that supports the availability, affordability, and positive perception of generic medicines while ensuring consumers' rights to informed and fair choices.

Realizing Equity of Access through Law: The Role of Corporate Responsibility in the National Health Insurance System

Equity of access is a fundamental principle underlying the implementation of Indonesia's National Health Insurance system (JKN), ensuring that all individuals can obtain necessary health services without discrimination based on economic, geographic, or social factors. This requires adequate healthcare facilities and supporting infrastructure, including medicines and medical devices (Baan & Madjid, 2020). Within the legal framework, Law Number 40 of 2004 on the National Social Security System (SJSN) establishes JKN as a mandatory system based on the principle of mutual cooperation (gotong royong). Under this principle, pharmaceutical corporations are not merely market actors but stakeholders responsible for supporting the sustainability of the system. Practices such as excessively high pricing of patented medicines or obstructing the availability of generics may undermine this principle and threaten the financial stability of JKN.

To operationalize equitable access, the government uses policy instruments such as the National Formulary issued by the Ministry of Health, which serves as a binding list of medicines for healthcare facilities participating in JKN. Inclusion in the formulary provides pharmaceutical companies with access to a large market but also requires adherence to affordability principles. Unilateral price increases may violate the principle of good faith in relations with BPJS Kesehatan and the Ministry of Health. Addressing health inequalities is also essential for designing effective policy solutions (Nalin et al., 2022). Transparent price negotiations and health technology assessments therefore become key mechanisms linking market operations with public service obligations.

When market mechanisms fail to ensure affordability, stronger legal instruments may be applied. Compulsory licensing under Article 109 of the Patent Law allows the government to produce or import generic medicines when patented medicines are unaffordable. This mechanism places public interest above exclusive patent rights and requires patent holders to negotiate in good faith and offer reasonable pricing or royalty terms. Legal responsibility in healthcare practices, such as in immunization programs, also demonstrates the importance of accountability in protecting public health (Riyanto et al., 2023). Ultimately, the Patent Law affirms that patent exclusivity remains subject to public interest and government oversight to guarantee equitable access to medicines.

The dimension of equitable access is closely related to consumer rights in obtaining adequate information. The transparency obligations mandated by the Consumer Protection Law gain a new dimension within the JKN ecosystem. Consumers within the JKN system are both contributors who pay premiums and beneficiaries who receive services. Therefore, their right to information extends beyond information about a single product; they also have the right to understand the implications of drug choices for the sustainability of the system that they collectively finance. Public education campaigns conducted by BPJS Kesehatan and the Ministry of Health regarding the importance of using generic medicines represent an implementation of this collective right to information. Pharmaceutical corporations, particularly patent holders, have a responsibility not to engage in marketing activities that directly or indirectly weaken this public health message. For instance, sponsoring medical events that exclusively discuss the advantages of branded medicines without balanced context regarding the role of generics within the JKN system may be considered a practice that harms collective consumer interests. Expanding equitable access to health services through telemedicine also demonstrates the importance of innovation in reaching communities

across various regions (Khayru & Issalillah, 2022). Oversight by the National Agency of Drug and Food Control (Badan POM) over pharmaceutical promotion should broaden its scope to ensure that industry-funded educational activities do not contradict national drug policy and the principle of equitable access within JKN. Within this framework, information becomes a policy instrument that determines the sustainability of the system.

The structure of the JKN market requires a contextual approach to the enforcement of competition law. The application of competition law within the JKN system must consider its unique market structure. The JKN market functions as a large monopsony, where BPJS Kesehatan acts as a single buyer representing hundreds of millions of participants. Corporate behaviour within such a market must be analysed using a different framework compared to retail markets. The application of Indonesian positive law in combating fraud and falsification in health insurance demonstrates the importance of protecting both the industry and consumers (Setiawan et al., 2023). Practices such as secret agreements among producers to avoid intense competition in e-catalo tenders, or market allocation agreements for certain medicines listed in the formulary, pose direct threats to equitable access because they undermine the market mechanisms designed to reduce prices. The Business Competition Supervisory Commission (KPPU) plays a strategic role in overseeing market concentration at the upstream level (manufacturers) and potential collusion in public procurement for JKN. Competition law enforcement in this context directly protects the JKN budget, which ultimately safeguards access for all participants. Corporate responsibility therefore includes avoiding any form of collusion, whether horizontal or vertical, that could distort transparent and competitive procurement processes. In this way, competition law becomes an instrument for protecting access rather than merely ensuring market efficiency.

The management of financing risks associated with high-cost diseases requires a new model of relationship between the state and the pharmaceutical industry. The concept of shared responsibility in managing population health risks is particularly relevant. Catastrophic diseases such as cancer or hepatitis C require innovative medicines that are extremely expensive. Mechanisms such as managed entry agreements (MEA) or risk-sharing agreements between BPJS Kesehatan and pharmaceutical companies represent an operationalization of equitable access through sophisticated legal negotiation. Under such agreements, pharmaceutical companies may accept lower prices in exchange for guaranteed volumes or payments linked to treatment outcomes (outcome-based payments). Corporate responsibility is reflected in the willingness to negotiate constructively and transparently regarding effectiveness data and financing models, recognizing that the sustainability of the JKN system is a shared interest (Trisnantoro, 2018). These agreements must be designed in good faith, avoiding excessive confidentiality clauses that could hinder public accountability in the use of JKN funds. This model positions collaboration as a prerequisite for sustainable access.

The technical aspects of pharmaceutical regulation serve as the foundation of public trust in generic substitution policies. Standards and oversight by the National Agency of Drug and Food Control (Badan POM), particularly regarding the bioequivalence of generic medicines, constitute a technical prerequisite for equitable access. Without trust in the quality of generics, substitution policies within JKN healthcare facilities will not function effectively. The responsibility of generic drug manufacturers is absolute in complying with Good Manufacturing Practices (CPOB) and demonstrating bioequivalence. At the same time, patent-holding companies have a responsibility not to actively spread unfounded doubts regarding Indonesia's generic regulatory system. Lobbying efforts aimed at imposing bioequivalence requirements beyond internationally accepted scientific standards, with the intention of obstructing competition, may be viewed as a barrier to equitable access. Legal implications and challenges related to the use of medical records as evidence in the Indonesian judicial system also demonstrate that procedural and evidentiary aspects play an important role in the enforcement of health law (Ustani et al., 2024). In performing its role as an independent regulator, the National Agency of Drug and Food Control must ensure that regulatory standards both protect patients and do not become tools for unhealthy market protection. Technical regulation thus has direct implications for market structure and patient access.

At the level of healthcare service implementation, the behaviour of actors within healthcare facilities becomes the final determinant of policy success. At the healthcare facility level, national drug policy requiring prescriptions to be written using generic names and allowing pharmacist substitution (where permitted) serves as

the final operational instrument. The effectiveness of this policy depends heavily on the behaviour of pharmaceutical corporations at the downstream level. Ethical and legal regulations governing the documentation of medical records by physicians are essential for maintaining accountability in healthcare services (Mubarak et al., 2023). In practice, transactional relationships between pharmaceutical companies, pharmacies, and physicians through financial incentives can distort prescribing decisions, encourage monopolistic tendencies, and increase drug prices borne by patients. Such practices not only undermine the professional independence of healthcare providers but may also be legally classified as bribery. The provision of incentives or gifts to doctors and pharmacists to influence prescriptions or dispensing decisions contradicts professional ethics and undermines policy objectives. The Health Law and the Codes of Medical and Pharmaceutical Ethics already prohibit such practices. Legal enforcement against violations by corporations, not only against individual healthcare professionals, is therefore essential. Pharmaceutical companies must implement strong compliance programs to prevent their employees or representatives from engaging in practices that distort rational choices at healthcare facilities. Such distortions directly undermine the principle of equitable access by diverting resources from cost-effective medicines to more expensive alternatives. Integrity in practices at the service level is therefore fundamental to maintaining equitable access.

When examined at the systemic level, equitable access requires an integrated enforcement architecture. Overall, the operationalization of equitable access through corporate responsibility law within the JKN system is ecosystemic in nature (Trisnantoro, 2018). It requires coordinated interpretation and enforcement of various laws, with BPJS Kesehatan and the Ministry of Health serving as focal institutions with direct stakes in the system's sustainability. Class action lawsuits initiated by BPJS Kesehatan against pharmaceutical companies proven to have engaged in practices that harm the system such as antitrust violations or civil claims for financial losses could become powerful enforcement instruments. Such actions would send a clear message that corporate responsibility toward the JKN system is tangible and legally enforceable in court. In addition, incorporating specific social responsibility clauses into legally binding pharmaceutical procurement contracts for JKN could serve as a mechanism to internalize the principle of equitable access directly within contractual relationships. This approach strengthens the state's legal position in safeguarding the sustainability of the system.

The effectiveness of this entire framework ultimately depends on the active role of regulators. The operationalization of equitable access also relies heavily on the institutional capacity and political will of regulatory bodies. Regulators must view pharmaceutical corporations not merely as neutral business entities, but as actors with significant influence over the achievement of national health system goals. Proactive oversight of market structures, analysis of the impact of pricing policies on the JKN budget, and investigations into systemic complaints regarding barriers to generic drug access should become part of routine regulatory functions. Studies also show that patients' intentions to visit hospitals are influenced by various factors, including viral marketing and word-of-mouth communication, highlighting the importance of reputation and public trust (Taufik et al., 2022). Within this paradigm, law enforcement is not purely reactive waiting for violations to occur but rather proactive in shaping an environment in which compliance with the principle of equitable access becomes a prerequisite for long-term business success in the Indonesian market. In this way, corporate responsibility law functions as a bridge connecting market logic with the imperative of social justice. It ensures that the forces of innovation and market efficiency operate in support of, rather than in opposition to, the collective goal of guaranteeing health for all. This framework ultimately affirms that equitable access is not the product of chance, but the result of consistent and publicly oriented legal governance.

CONCLUSION

The legal framework governing the corporate responsibilities of pharmaceutical companies in the distribution of generic and branded medicines in Indonesia is built through a combination of patent law, health law, consumer protection law, and competition law. This system aims to balance incentives for innovation with the need for affordable access to medicines, particularly within the National Health Insurance (JKN) system. Although the legal framework is normatively adequate, its implementation still faces challenges, such as corporate strategies (e.g., patent thicket, product hopping, and biased promotional practices) that may limit access to generic medicines and increase healthcare costs.

The implications of this study highlight the need for stronger regulatory coordination among

government institutions, BPOM, KPPU, BPJS Kesehatan, and other relevant bodies to oversee drug pricing, marketing practices, and competition in the pharmaceutical sector. Pharmaceutical companies are also encouraged to integrate social responsibility into their business strategies rather than merely complying with minimum legal requirements.

Key recommendations of this research include establishing an inter-agency coordination forum to monitor access to generic medicines, strengthening patent regulations to prevent evergreening practices, improving BPJS Kesehatan's capacity to negotiate drug prices, developing specific competition guidelines for the pharmaceutical sector by KPPU, and enhancing consumer education regarding the right to information and access to medicines.

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