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Medical Advertising Regulations and Patient Protection as Consumers of Healthcare Services

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ABSTRACT

This article examines regulations on advertising and promotion of medicines and medical devices through normative legal analysis, focusing on the tension between freedom of enterprise and protection of patients as consumers of health services. The legal materials analysed include laws in the fields of health, consumer protection, trade, hospitals, and electronic information and transactions, accompanied by implementing regulations from the Ministry of Health and the National Agency of Drug and Food Control (BPOM). Academic literature on health law, consumer law, patient safety, and regulatory theory is used to construct a theoretical framework that explains the legitimacy of restrictions on medical advertising and protection against misleading information. The results of the study show that freedom of enterprise is recognised, but is considered a conditional freedom. The Health Law and BPOM regulations stipulate the obligation to provide truthful and complete information in advertisements for medicines and medical devices, while the Consumer Protection Law affirms the right of patients to honest information and the possibility of claiming compensation when losses occur due to misleading information. The Trade Law and Hospital Law regulate promotion within the framework of business practices and ethical service obligations, while the Electronic Information and Transactions Law extends the regulation to the digital space. Legal protection for patients is built through a combination of preventive, corrective, and repressive instruments. Preventive instruments are realised through the regulation of the substance and procedures of promotion. Corrective instruments take the form of civil liability and administrative mechanisms that allow for the withdrawal or prohibition of advertisements. Repressive instruments are available when misleading information exceeds limits and constitutes a criminal offence. The analysis highlights the importance of documenting promotional materials, accessible complaint mechanisms, and ethical awareness among healthcare professionals and service facility managers. This article concludes that the national regulatory framework has led to relatively comprehensive protection for patients, but its effectiveness is highly dependent on consistent enforcement, coordination between authorities, and improved legal and health literacy among the public.

INTRODUCTION

The development of the pharmaceutical and medical device industries over the past two decades has shown intensive growth in terms of both product innovation and market expansion. In various countries, including those with legal systems that recognise freedom of enterprise, the promotion of medicines and medical devices has become a key instrument for introducing new products to healthcare professionals and the public (Jacob, 2018). The transformation of media from print to digital and algorithm-based platforms has changed the pattern of commercial communication so that advertising messages can target very specific groups based on behavioural data. This situation raises questions about the extent to which commercial messages can be allowed to operate through market mechanisms, and when the state is obliged to intervene with regulations to avoid misleading information, exaggerated claims about efficacy, or obscuring the risks of using medical products (Li & Gibbs, 2021).

In the field of medicine and medical devices, the

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issue becomes more complex because the objects being promoted are directly related to the body, health, and often the survival of patients. Prescription drugs, biotechnology products, and high-tech medical devices carry risk characteristics that are not easily understood by the general public. This tension can be seen through the lens that technology, including in the field of information promotion, must be implemented with principles that support the efficiency and reliability of governance, rather than creating information distortion (Arifin & Putra, 2022). On the one hand, there are the interests of manufacturers and health care facilities to utilise commercial promotion to expand market share and recoup research investments. On the other hand, there is the vulnerability of patient consumers who are in an asymmetrical position in terms of medical knowledge, access to neutral information, and the ability to assess persuasively packaged efficacy claims (Peráček et al., 2019). This imbalance has prompted many legal systems to adopt specific restrictions on medical advertising that is considered to have the potential to interfere with the rationality of patient and healthcare professional choices.

Academic studies on drug advertising show that commercial promotion risks shifting the orientation of drug use from clinical need to preferences shaped by marketing messages (Pashkov & Harkusha, 2017). This phenomenon is consistent with concerns in the social literature about how unbalanced or misleading information can erode trust within a community (Issalillah, & Hardyansah, 2022). Analysis of prescription drug advertising in various jurisdictions shows that claims of benefits are often emphasised more strongly than the presentation of risks, while the nuances of scientific uncertainty regarding evidence of effectiveness are rarely presented proportionally (Mintzes, 2012). In the realm of consumer law, the discourse on fair information asserts that consumers have the right to honest, clear, and non-misleading information about product characteristics, including limitations and potential dangers of use (Howells et al., 2018). The intersection of health studies and consumer law emphasises the need for a regulatory framework that balances commercial incentives with patient protection obligations.

In everyday life, patients live amid a flood of messages that blur the line between public health information and covert promotion. Brochures, posters in health facilities, television broadcasts, social media content, and even "user" testimonials are often designed with marketing aesthetics that seek to build high expectations for certain medical products. Narratives of quick healing, symptom reduction without significant risk, or claims of innovation are often presented without adequate explanation of the conditions of use, contraindications, and limitations for patient groups who should not actually consume the product. In situations of information asymmetry, patients tend to trust symbols of authority such as white coats, health institution logos, or scientific terms inserted in advertisements. This reinforces the argument that the regulation of drug and medical device advertising is not merely a matter of freedom of enterprise, but is closely related to professional ethics, public health governance, and the rights of patients as consumers of health services who deserve protection.

The first prominent issue relates to the tension between freedom of enterprise in the pharmaceutical and medical device sectors and the principle of patient consumer protection. This dynamic is essentially part of the broader challenge of business sustainability, in which businesses must continue to adapt and demonstrate competence within an evolving regulatory framework (Mardikaningsih et al., 2022). Manufacturers and business actors argue that promotion is a legitimate part of market competition and is necessary for therapeutic innovations to become widely known. However, experience in various jurisdictions shows that drug advertising, especially that targeting the public, often simplifies complex clinical issues into messages that emphasise benefits and reduce risks (Mintzes, 2012). From a consumer law perspective, this pattern of communication has the potential to lead to misleading information, i.e. information that appears to be correct but leads consumers to misunderstand the quality or safety of a product (Howells et al., 2018). The lack of a clear boundary between acceptable promotion and information manipulation is a source of recurring regulatory debate.

The second issue relates to the position of patients as consumers of healthcare services who face highly asymmetrical market structures and information. Unlike consumers of ordinary products, patients are often in a state of distress, lack technical knowledge, and rely on the recommendations of healthcare professionals who may also be exposed to intensive promotion from the industry. In such situations, advertising messages for medicines and medical devices can influence patients' expectations of therapy, drive demand for more expensive branded products, or divert attention from non-pharmacological therapy options that may be more

appropriate. Critical studies of drug advertising highlight that promotions relying on emotional narratives and personal testimonials tend to ignore the nuances of scientific evidence and the benefit-risk ratio that should form the basis of clinical decision-making (Mintzes, 2012).

A third issue arises in the regulatory sphere when countries need to formulate standards for restricting advertising and promotion without eliminating all the freedom of enterprise guaranteed by the economic legal regime. Many legal instruments impose explicit prohibitions on exaggerated claims, misrepresentation, or obscuring of important information, but translating these general norms into operational parameters often presents difficulties. Assessing whether an advertising message is misleading requires analysis of how consumers perceive the message, the language structure, visual appearance, and the average knowledge background of consumers (Howells et al., 2018). In the case of medicines and medical devices, the complexity increases because the ethical guidelines of the healthcare profession, scientific evidence standards, and regulatory differences between over-the-counter medicines, prescription medicines, and high-risk medical devices must also be taken into account.

Changes in the digital communication landscape have accelerated the circulation of advertisements for medicines and medical devices through channels that are difficult to monitor using traditional regulatory mechanisms. Paradoxically, amid the media's role in raising public awareness, including about basic rights, the digital environment has also opened up new spaces for communication practices that have the potential to exploit vulnerabilities (Hardyansah et al., 2022). Online platforms enable cross-border content distribution, the use of influencers, and the utilisation of behavioural data to tailor messages to the vulnerabilities of target groups. In this context, the legal framework designed for conventional media risks becoming inadequate in the face of new forms of covert promotion, such as branded educational content or commercial partnerships with healthcare facilities. A normative legal analysis of medical advertising regulations is highly relevant to examine the extent to which existing norms are still in line with developments in promotional practices and to identify regulatory gaps that could potentially harm patients as consumers.

In addition, various reports on the burden of healthcare costs and irrational drug use show that clinical decisions and service-seeking behaviour are influenced by complex interactions between information, trust, and economic incentives. Amidst efforts by the healthcare system to promote the rational use of drugs and avoid unnecessary interventions, aggressive promotion of certain products has the potential to encourage consumption patterns that are not in line with scientific considerations. In such situations, clear regulations regarding advertising limits, mechanisms to prevent misleading information, and the recognition of patients as consumers who are entitled to honest information are an important part of the agenda for reforming health and consumer law.

This study aims to conduct a normative legal analysis of the regulatory framework for advertising and promotion of medicines and medical devices, placing the tension between business freedom and patient consumer protection at the centre of the analysis. Theoretically, the study is expected to enrich the study of health law and consumer law by mapping arguments regarding the legitimacy of restrictions on medical advertising and strengthening the construction of patients as consumers of health services. In practical terms, the results of the analysis are expected to provide an argumentative basis for policymakers, supervisory agencies, and stakeholders in the health sector to assess the adequacy of existing regulations and to design mechanisms to prevent misleading information in the promotion of medicines and medical devices.

RESEARCH METHOD

This study uses a normative juridical approach with a qualitative literature study design that focuses on analysing legal materials and scientific publications related to advertising regulations, drug promotion, medical devices, and patient consumer protection. Primary legal materials include laws, government regulations, and sectoral regulations in the fields of health and consumer protection, while secondary legal materials include books, journal articles, and reports from relevant international institutions. A qualitative literature study approach was chosen because it provides space to interpret legal texts and academic papers systematically through repeated reading, comparison, and structured meaning extraction (Creswell & Poth, 2018). The analysis was conducted with an emphasis on traceability of arguments, so that each legal conclusion was supported by a normative basis and theory clearly related to the issues of medical advertising, misleading information, and the position of patients as consumers of health services.

Literature data collection was conducted through searches of scientific databases such as Scopus, Web of Science, and Google Scholar. Inclusion criteria included scientific publications and academic books from the last two decades that contained explicit discussions on the regulation of drug or medical device advertising, patient consumer protection, and normative legal analysis methodologies. Publications that did not provide references that could be verified through DOI or ISBN, or that originated from journals of unclear scientific quality, were excluded from the main analysis material to maintain the integrity of the references (Snyder, 2019). The collected legal materials and literature were then classified into thematic groups, such as the fundamentals of consumer law, medical promotion ethics, restrictions on drug advertising, and the position of patients in health law.

The analysis process used a thematic synthesis approach adapted from Braun and Clarke (2006) and document analysis techniques as described by Bowen (2009). The initial step involved a thorough reading to obtain an overview of the argument structure of each source, followed by preliminary coding of text units related to three main clusters: freedom of enterprise in medical promotion, prevention of misleading information, and protection of patients as consumers. These codes were consolidated into broader analytical themes, such as the legitimacy of advertising restrictions, standards of truthfulness of information, and the bargaining position of patients. To maintain quality, the coding and synthesis processes were repeated until consistency between sections was achieved, while the findings were tested conceptually by comparing them to the selected legal frameworks of health law and consumer law (Bowen, 2009; Braun & Clarke, 2006). In this way, the study sought to ensure that the resulting normative constructions were not disconnected from the empirical and theoretical foundations established in the literature.

RESULT AND DISCUSSION

Balancing Business Freedom and Restrictions on Medical Advertising

Advertising and promotion of medicines and medical devices fall within a legal framework that balances business freedom with patient protection. The legal framework governing the advertising and promotion of medicines and medical devices seeks to regulate business freedom through a set of normative boundaries oriented towards protecting patients as consumers. Theoretically, modern economic law recognises that markets require freedom of enterprise for innovation and competition to flourish, but regulation is needed when commercial activities pose significant risks to the public interest (Baldwin et al., 2012). According to Delmas, advertising for health services can threaten the relationship of trust that underpins health services, have a significant negative impact on doctors and the community, and undermine the interests of health services (Santas et al, 2017). In the health sector, these risks are directly related to patient safety and autonomy, so the promotion of medicines and medical devices cannot be left solely to the logic of marketing. Law No. 7 of 2014 on Trade provides the basis for recognition of freedom of enterprise and promotional practices, while Law No. 36 of 2009 on Health contains explicit prohibitions on misleading drug advertising and requires the accuracy of information. Both demonstrate that legislators seek to balance commercial incentives with special obligations of caution for products that touch on health. Thus, regulations serve to keep commercial incentives in line with public safety and trust.

Freedom of enterprise in medical promotion must always be framed by the principles of honesty and transparency of information. From a consumer protection perspective, freedom of enterprise is always accompanied by the requirement that businesses provide honest, clear, and non-misleading information. Consumer law literature emphasises that the relationship between businesses and consumers is characterised by information asymmetry, making the prohibition of misleading information a key pillar in safeguarding the rationality of consumer choices (Howells et al., 2018). Law No. 8 of 1999 on Consumer Protection places patients as consumers of health services who are entitled to accurate information about the goods and services they receive, including medicines and medical devices promoted through various media. Thus, freedom of enterprise in medical promotion is only legitimate to the extent that it does not sacrifice patients' right to information and does not create illusions of safety or effectiveness that exceed the available scientific evidence (Howells et al., 2018). Thus, the legitimacy of promotion only applies if patients' right to accurate information is guaranteed.

Drug advertising often creates perceptual bias by emphasising benefits and downplaying risks. Empirical experience in various countries shows that drug advertising easily encourages perceptual bias towards benefits over risks. A study of prescription drug advertisements found that promotional messages tended to emphasise claims of

effectiveness and downplay exposure to side effects, even when regulations required balanced information (Mintzes, 2012). Within the regulatory theory framework, this condition illustrates what is known as first-order regulatory failure, where rules are general in nature while their implementation faces industry creativity in designing messages that are persuasive and difficult to detect through routine monitoring (Hood et al., 2001). In Indonesia, similar threats are addressed through provisions in the Health Law and regulations from the Food and Drug Supervisory Agency (BPOM) that prohibit unproven claims, false testimonials, or the presentation of information that could mislead patients' judgements. Therefore, health regulations and the BPOM are in place to ensure that promotions remain honest and balanced.

BPOM Regulation No. 8 of 2019 provides clear operational limits for advertising health products. More specifically, BPOM Regulation No. 8 of 2019 concerning the Supervision of Advertising of Medicines, Traditional Medicines, Health Supplements, Cosmetics, and Processed Foods establishes operational parameters regarding what constitutes misleading claims in advertisements for medicines and other health-related products. This approach is in line with literature findings that indicate the need for clear technical standards so that supervisory authorities can take action against violations without getting caught up in overly broad interpretations (Baldwin et al., 2012). On the other hand, the existence of these standards provides certainty for business actors regarding the limits of acceptable promotion, so that business freedom can still be exercised as long as ethical and scientific requirements are met. In other words, the regulation serves as a fence that limits manipulative practices, rather than eliminating promotion altogether. Thus, the regulation functions as an ethical fence that prevents manipulation without eliminating promotion.

Health service advertisements must be proportionate and not excessive, according to Minister of Health Regulation No. 62 of 2017 concerning Health Service Advertisements and Publications, which reinforces this orientation by regulating the procedures for health service advertisements so that they are not excessive or solely commercial in nature. Health service advertisements are a form of persuasive communication to introduce health policies, programmes, and/or services to the public. (Widyorini, 2020). Studies on the relationship between aggressive promotion and the use of health services show that medical service advertisements have the potential to drive demand that is not always in line with clinical needs, for example by highlighting certain procedures or technologies that are described as the best options without balanced explanations (Mintzes, 2012). By stipulating the obligation to include accurate and proportionate information, as well as prohibiting bombastic claims of healing, the Minister of Health Regulation plays a role in directing health service promotion to remain within the educational corridor (Amin et al., 2020). Here, it is apparent that the freedom of healthcare facilities to communicate their services is framed by the interest of protecting patients from the risks of making decisions based on expectations created by advertising. Therefore, the promotion of healthcare services is directed to be in accordance with the principles of education and patient protection.

Through the ITE legal regime, health promotion practices in the digital space are organised more systematically. The balance between business freedom and patient protection is further strengthened by the legal regime of electronic information and transactions. Law No. 11 of 2008 in conjunction with Law No. 19 of 2016 concerning Electronic Information and Transactions expands the scope of regulation to the digital realm, including the dissemination of advertisements for medicines and medical devices via the internet, social media, and electronic trading platforms (Hatta et al., 2021). Research on online drug advertising shows that the digital environment facilitates the spread of exaggerated claims, cross-border promotion, and consumer segmentation based on behavioural data that is difficult to monitor with traditional regulatory instruments (Donohue et al., 2007). By qualifying electronic information as a regulatory object and providing a basis for action against misleading content, the ITE legal regime becomes an important instrument for ensuring that the expansion of business freedom into the digital realm does not neglect the principle of patient consumer protection. Thus, online business freedom continues to be exercised within the corridor of patient consumer protection.

BPOM Regulation No. 30 of 2017 emphasises the conformity of medical device advertisements with distribution permits. Another dimension of this balance is evident in regulations governing the promotion of medical devices. BPOM Regulation No. 30 of 2017 concerning the Supervision of Advertising of Medical Devices and Household Medical Supplies stipulates that all advertising messages must be in accordance with the distribution permit and

technical documents accompanying the product. The literature on medical device policy emphasises that claims regarding the performance and benefits of a device are highly dependent on specific technical parameters and clinical trials, so that distortion of information at the advertising level can lead to the use of products outside their indications or in inappropriate populations (Greenhalgh et al., 2017). By requiring advertisements to be consistent with technical data that has been assessed by the authorities, this regulation limits the scope for promotional creativity that could potentially blur the line between potential benefits and the actual scientific evidence available. Therefore, promotion is restricted so as not to exceed the valid scientific evidence.

Regulatory theory highlights the influence of industry in shaping health promotion regulations. Within the realm of regulatory theory, freedom of enterprise in the pharmaceutical and medical device sectors is often linked to the power of industry as a political actor capable of influencing regulatory design. Abraham (2002) demonstrates how the pharmaceutical industry can exploit the discourse of innovation and patient needs to oppose promotional restrictions that are considered to hinder the dissemination of information about new drugs. In Indonesia, similar tensions are anticipated through a combination of regulations at the level of the Law and implementing regulations that explicitly place patient safety and interests as the main reference. The existence of the Hospital Law and the Minister of Health Regulation on health service advertising shows that health facilities are not viewed solely as business entities, but rather as institutions bound by ethical standards, accreditation, and additional principles of prudence when dealing with public communication. Thus, regulations emphasise that health facilities must comply with patient ethics and safety.

Consumer protection is strengthened through legal liability for misleading advertising. The framework for protection against misleading information is further strengthened by civil and administrative liability provisions. The Consumer Protection Law opens up the possibility for patients who have been harmed by misleading advertising to seek compensation, while administrative sanctions such as warnings, revocation of distribution permits, or advertising bans are regulated in regulations issued by the Ministry of Health and the Indonesian Food and Drug Administration (BPOM). The literature on consumer protection emphasises that the effectiveness of prohibitions on misleading information depends on the availability of credible enforcement mechanisms, including complaint procedures and sanctions that are severe enough to create a deterrent effect (Howells et al., 2018). On the other hand, the threat of legal liability encourages businesses to develop internal procedures to review advertising material from a legal and ethical perspective before publication, making legal risk management part of corporate governance. Thus, sanction mechanisms and internal governance are key to preventing legal risks.

The health legal framework requires internal compliance in product promotion. The balance sought by this legal framework has real managerial implications for the pharmaceutical industry, medical device manufacturers, and hospital managers. Companies need to develop internal compliance involving legal, ethical, and marketing units so that all promotional material is tested against the standards set by the Health Law, Consumer Protection Law, ITE Law, and sectoral regulations. This approach is in line with the idea that modern regulations encourage organisations to become responsible risk managers, rather than merely objects of external supervision (Hood et al., 2001). In other words, freedom of enterprise is recognised, but framed by the obligation to manage the risk of misleading information as an integral part of reputation management and business sustainability in the health sector. Thus, business freedom is limited by the obligation to manage the risk of misleading information.

The national legal framework demonstrates a systematic effort to regulate the promotion of health products. Furthermore, the integration of these various legal instruments creates a layered regulatory architecture that reduces the possibility of regulatory gaps. The Health Law substantively regulates the prohibition of misleading advertising, the Consumer Protection Law provides the basis for the right to accurate information and compensation, the Trade Law recognises the framework for promotion in the flow of goods, the ITE Law extends its reach to the digital realm, while the Minister of Health Regulation and BPOM regulations fill in the technical details. This layered approach is in line with the idea of tiered regulation presented by Baldwin and colleagues, namely that issues with complex technical and social dimensions require a combination of general norms and detailed guidelines in order to be applied consistently (Baldwin et al., 2012). In practice, companies operating in the field of medicines and medical devices must navigate all layers of regulations when

designing advertising and promotion strategies. This emphasises that regulatory compliance is a key prerequisite for business sustainability in the health sector.

The discourse on health product promotion always places regulation as an instrument that balances business interests and public protection. Normatively, it can be concluded that the Indonesian legal framework seeks to place freedom of enterprise in the promotion of medicines and medical devices as conditional freedom. The state provides space for business actors to communicate their products to the public, but requires that such communication must comply with standards of truthfulness, propriety, and protection of patients from the risk of misrepresentation. This principle is in line with the view that the health market differs from ordinary commodity markets because the object of the transaction concerns the right to health and life. Therefore, regulatory intervention in the form of restrictions on medical advertising is not seen as an arbitrary restriction on business freedom, but rather as a balancing mechanism to ensure that market structures do not sacrifice the interests of the most vulnerable parties, namely patients. Thus, regulations are not intended to restrict, but rather to ensure that business freedom remains in line with fundamental rights to health.

The implementation of regulations in daily practice requires a balance between legal norms and industry dynamics. At a practical level, this balance will only be maintained if normative provisions are supported by consistent interpretation and firm enforcement. Without adequate supervision, businesses risk testing the limits of norms by designing promotional messages that are creative but potentially misleading. On the other hand, overly rigid or restrictive interpretations can hinder efforts to disseminate information that is beneficial to patients, such as the existence of new therapies that are scientifically proven to be effective. The challenge for policymakers and regulators is to maintain a clear line between legitimate promotion and misleading information, while providing legal certainty for the industry and real protection for patients. The legal framework that has been established provides a strong foundation, but its successful implementation is highly dependent on consistency, transparency, and sensitivity to industry dynamics and patient needs. Thus, the effectiveness of regulations depends on the ability to maintain a balance between legal certainty and patient needs.

Consumer Protection for Patients against Misleading Information in Medical Promotions

In general, legal protection for patients as consumers of health services requires clarity of norms and certainty in practice. Legal protection for patients as consumers of health services is still very weak, and even the regulations in the law are unclear (Jadda, 2017). The construction of legal protection for patients as consumers of healthcare services stems from the recognition that patients have the right to accurate and understandable information about health-related products and services (Jaszczuk, 2018). Within the framework of the right to health, access to accurate information is seen as a prerequisite for individuals to make autonomous decisions regarding medical interventions (Gostin & Wiley, 2016). Law No. 8 of 1999 concerning Consumer Protection affirms the right of consumers to honest and non-misleading information about the condition and warranty of goods or services, while Law No. 36 of 2009 concerning Health requires the presentation of accurate information about medicines. If the information in medical advertisements or promotions deviates from these standards of truthfulness, then legal protection targets not only the product as an object, but also the message that influences the patient's choice (Widyorini, 2020). Here, patients are positioned not merely as passive recipients, but as legal subjects who have claims against business actors and health service providers when their right to information is violated. Thus, strengthening the legal framework is important so that the position of patients as consumers is truly protected.

The dimension of legal protection in health promotion cannot be separated from the aspect of patient safety. The dimension of patient rights in medical promotion is intertwined with the idea of patient safety developed by international organisations. This is highly relevant because one of the main factors that shape patient satisfaction in public services, including health, is guaranteed and safe service quality (Khayru & Issalillah, 2022). The World Health Organisation (WHO) defines patient safety as "the prevention of errors and adverse effects that are harmful to patients related to health services" and "not harming patients" (Lawati et al., 2018). The WHO emphasises that patient safety includes protection from hazards arising from the service system, including misinformation that triggers the inappropriate use of medicines or medical devices (World Health Organization, 2011). Runciman and colleagues underscore that safety incidents often stem from communication failures, whereby clinical

information or explanations about therapy are not conveyed accurately (Runciman et al., 2009). Within a normative legal framework, medical advertising and promotion that makes false claims about benefits or obscures risks can be interpreted as a form of communication failure that has the potential to cause safety incidents (Syafruddin, 2022). Thus, consumer protection and health law regimes converge at the same point, namely preventing patients from being exposed to risks arising from flawed information. Ultimately, the accuracy of information is a fundamental prerequisite for ensuring patient safety in all medical promotional practices.

In the context of medical promotion, compensation mechanisms play an important role in maintaining the accountability of business actors. Legal protection for patients as consumers is manifested in the form of civil liability when misleading information causes harm (Syafruddin, 2022). Health rights literature indicates that civil litigation can serve as a corrective measure to restore individual losses while sending a normative signal that certain practices exceed acceptable limits (Flood & Gross, 2014). Under the Consumer Protection Act, patients who are harmed by misleading advertisements have grounds to seek compensation from businesses that produce, distribute, or promote medicines and medical devices. This instrument strengthens the bargaining position of patients, who are structurally weak when dealing with large corporations. From a normative legal analysis perspective, the recognition of the right to compensation affirms that misleading information is not treated as a mere ethical violation, but rather a form of legal violation against consumers. Thus, civil mechanisms serve as an important pillar to ensure that health promotion practices remain within the corridor of the law.

At the law enforcement level, protection for patients does not only take place through individual civil channels. In addition to individual compensation, the construction of legal protection opens up space for collective action when misleading advertising practices affect a large group of patients. Flood and Gross note that in disputes related to health rights, class action mechanisms can be a means of negotiating service standards or policies that affect many people at once (Flood & Gross, 2014). In the realm of medical promotion, a similar idea can be applied when an advertising campaign causes a similar pattern of harm to many patients, such as the purchase of expensive drugs whose efficacy is not as promised or the use of medical devices that turn out to have undisclosed risks (Hatta et al., 2021). Normatively, the possibility of such collective action strengthens the function of legal protection, as the burden of proof and the costs of the process are no longer borne by individual patients. Thus, this mechanism expands access to justice while increasing accountability in medical promotion practices.

Within the framework of enforcing health promotion standards, administrative instruments play an equally important role. Patient legal protection is also articulated through administrative sanctions imposed on businesses, health facilities, or health workers who violate promotion regulations. In regulatory theory, administrative sanctions are seen as an important instrument for correcting behaviour without always bringing cases to the criminal or civil courts, while also sending a regulatory signal to other market players (Baldwin et al., 2012). Minister of Health Regulation No. 62 of 2017 and BPOM regulations on advertising supervision give authorities the power to issue warnings, stop advertisements from being aired, and even revoke product distribution permits. From the patient's perspective, the existence of this administrative mechanism means that the state can proactively act to stop the exposure of misleading information before the damage spreads, rather than waiting for a lawsuit to arise. Thus, administrative sanctions strengthen the preventive function of the supervisory system and ensure that promotional practices remain within the corridor of patient consumer protection.

Within the spectrum of health promotion oversight, the penal approach serves as an ultimum remedium mechanism that is applied only under certain conditions. The criminal realm provides an additional layer of protection when misleading information in medical promotions reaches the level of fraud or seriously harms the public interest. Medical advertisements in electronic media play a significant role in shaping public perception compared to other media, as promotions are often carried out by manufacturers through electronic media such as television, radio, and the internet (Mujiati et al., 2022). The ITE Law regulates the prohibition of disseminating misleading and harmful information to consumers through electronic systems, while general criminal provisions regarding fraud can be imposed if there is an element of intent to deceive the public for economic gain. Health law literature emphasises that the use of criminal sanctions in the health sector must be carefully considered, given the potential for deterrence and the risk of excessive criminalisation (Gostin & Wiley, 2016). However, in cases of medical promotion that systematically manipulates patient concerns or conceals

serious risks, the threat of criminal penalties serves as a hard line that affirms that there are forms of commercial behaviour that cannot be tolerated in the health system. Thus, criminal instruments remain relevant as enforcers of norms and protectors of the public against promotional practices that threaten patient safety.

Advances in information technology demand a broader perspective on the mechanisms for monitoring health promotion. Legal protections for patients become increasingly complex as medical promotion moves into the digital and cross-border realms. However, on the other hand, the same technological innovations also open up the potential for equal access to health services through mechanisms such as telemedicine (Khayru & Issalillah, 2022). The use of online platforms allows for the segmentation of advertisements based on behavioural profiles and health data, thereby increasing the potential for patient exposure to highly targeted messages. Kuner explains that cross-border data flows and personal data processing pose new challenges for privacy protection and national authority oversight (Kuner, 2013). When data on symptom searches or medical history is used to target specific drug advertisements, the line between health education and exploitation of vulnerability becomes blurred. Within a normative legal framework, patient protection requires an expanded interpretation of ITE regulations and data protection to include advertising targeting practices that risk directing patients towards therapeutic choices based on commercial algorithms rather than professional health considerations. Therefore, the regulatory framework in the digital age needs to be designed to anticipate and address the various new risks arising from the use of data and technology in medical promotion activities.

Medical promotion cannot be separated from the ethical responsibilities of hospitals and healthcare professionals. The role of hospitals and healthcare professionals is crucial in the construction of legal protection for medical promotion. Law No. 44 of 2009 on Hospitals requires hospitals to maintain the quality and ethics of their services, so that the form of promotion carried out by hospitals must be in line with these standards. Patient rights literature emphasises that healthcare institutions have a fiduciary duty to patients, meaning that patient interests must be prioritised over commercial interests when providing medical information or recommendations (Gostin & Wiley, 2016). If healthcare professionals or hospitals are involved in promoting certain products, for example by placing advertising material in healthcare facilities or providing recommendations influenced by commercial relationships with industry, legal protection requires transparency and the avoidance of conflicts of interest. This is important so that patients can distinguish between clinical advice and promotional messages. Thus, transparency and integrity are key to ensuring that promotion does not obscure the interests of patients.

Protecting patients from misleading medical advertising requires clear and effective access to complaint mechanisms. Patient-oriented legal protection also requires easily accessible complaint mechanisms. Experience in various countries shows that without effective complaint channels, many medical advertising violations never reach the enforcement stage because patients are unaware of their rights or the available procedures (Howells et al., 2018). Within a national framework, supervisory agencies such as the BPOM, health authorities, and consumer dispute resolution bodies need to be equipped with clear public information on the procedures for reporting misleading advertising (Hatta et al., 2021). From a normative legal analysis perspective, the right to protection only becomes real if procedural instruments that enable patients to seek redress and enforcement are available transparently and can be implemented without excessive obstacles. Thus, transparent complaint mechanisms ensure that patients' rights are truly protected in practice.

One important instrument in patient protection is the obligation to document medical promotions. Another aspect that strengthens patient protection is the obligation for businesses to document and track promotional materials. Snyder emphasises that a good documentation system is an important requirement in policy evaluation and accountability, as it allows for the tracing of the source and content of messages in circulation (Snyder, 2019). In the realm of medical promotion, the obligation to keep advertising scripts, broadcast evidence, and the scientific basis for claims used will facilitate the assessment process by authorities and courts in the event of a dispute. For patients, the existence of this documentary trail makes it easier to prove that the decision to use a drug or medical device was influenced by certain claims that were later proven to be false or exaggerated. Thus, documentation is not only an administrative obligation, but also part of the infrastructure for protecting patients as consumers. Therefore, well-organised documentation is the foundation of accountability and the protection of patient rights.

The legal framework for the protection of medical promotion is built by placing the patient at the centre of attention. Conceptually, the construction of legal protection for patients as consumers of health services against advertising and medical promotion practices establishes a network of obligations that bind manufacturers, distributors, health facilities, health

workers, and electronic system operators. This network places patients at the centre of consideration, with the assumption that their vulnerability in terms of knowledge and bargaining position must be compensated for through high information standards, multi-layered enforcement mechanisms, and the possibility of compensation for losses. A normative legal analysis of various laws and derivative regulations shows that this protection is designed to cover preventive (through advertising substance regulation), corrective (through compensation and sanctions), and repressive (through criminal penalties in serious cases) dimensions. Thus, this construction ensures comprehensive protection through preventive, corrective, and repressive approaches.

The effectiveness of legal protection in medical promotion depends on the awareness of all parties of their responsibilities. In practice, this protection will only be effective if all actors involved realise that medical promotion always has legal implications in addition to marketing dimensions. Any claims of efficacy, testimonials, or visualisations of therapeutic success broadcast to the public must be treated as legal statements that can be challenged when they result in patient harm. This awareness encourages a cultural shift from simply maximising the appeal of advertising to developing promotional materials that are in line with professional ethics and the principle of legal prudence. For patients, this legal protection mechanism provides assurance that when they respond to promotional messages in seeking treatment, the law acts as a safeguard against practices that exploit their hopes and uncertainties. Thus, regulation serves as a safety mechanism to ensure that medical promotion practices are conducted ethically and do not harm patients.

CONCLUSION

A normative legal analysis of regulations on advertising and promotion of medicines and medical devices shows that the legal framework in Indonesia strikes a balance between freedom of enterprise and the obligation to protect patients as consumers of health services. Laws in the fields of health, consumer protection, trade, hospitals, and electronic information and transactions, supplemented by implementing regulations from the Ministry of Health and the National Agency of Drug and Food Control (BPOM), set clear limits on exaggerated claims, misleading information, and promotional practices that could potentially compromise patients' rights to information and safety. This layer of protection is reinforced through the recognition of the right to accurate information, civil, administrative, and criminal liability mechanisms, and ethical obligations for health facilities and personnel. Thus, medical promotion is considered a legitimate activity as long as it adheres to standards of truthfulness, prudence, and respect for patient vulnerability.

Theoretically, this study emphasises the importance of interpreting medical advertising and promotion regulations as an integral part of both health law and consumer protection law, with a focus on patients' rights to information, safety, and compensation for damages. Practically, the findings suggest the need to strengthen oversight of promotional materials across various channels, including digital media, develop guidelines that are easily understood by businesses, and enhance the capacity of authorities to assess whether a message is misleading. For the pharmaceutical industry, medical device manufacturers, hospitals, and health workers, the implication is the need for internal governance that ensures all forms of promotion are in line with legal and ethical provisions, so that the risk of disputes and damage to public trust can be minimised.

Going forward, strengthening legal protection for patients as consumers of health services requires several steps. First, the government and regulatory authorities need to clarify the technical guidelines for assessing misleading information with concrete examples so that businesses have operational references. Second, public complaint mechanisms related to medical advertising and promotion need to be widely disseminated, accompanied by procedures that are simple and patient-friendly. Third, professional organisations and health education institutions need to include the issues of medical promotion and conflicts of interest in ethics education, so that health workers are sensitive when interacting with advertising material and commercial collaborations. Finally, further empirical data-based research is needed on patterns of medical advertising violations and patient experiences, so that regulatory updates are not speculative but based on measurable findings.

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