MARKETING | RESEARCH ARTICLE

Transforming Market-Driven Strategies in the Indonesian Medical Device Industry: Impact Analysis of Regulatory Compliance, Innovation, and Service Quality on Brand Loyalty

Marcell Wijaya Yudakusuma[1]

[1] Department of Management, Faculty of Business and Economy, Universitas Airlangga, Surabaya, Indonesia.
Email: marcell.wijaya.yudakusuma-2024@feb.unair.ac.id[1]

ABSTRACT

This study examines how regulatory compliance, product innovation, and service quality contribute to market-driven strategy transformation in the medical device industry and influence customers' brand loyalty, specifically in the Indonesian medical device industry. Data were collected using self-administered surveys from 120 institutional customers of a medical device manufacturing company in Indonesia as part of a quantitative research design and analyzed using structural equation modeling (SEM). The findings demonstrated that product innovation, service quality, and regulatory compliance all had significant effects on brand image ($p < 0.05$), with service quality being the most significant predictor ($\beta = 0.503$). Brand loyalty was positively and significantly impacted by brand image ($\beta = 0.587$; $p < 0.001$). Product innovation was found to have a significant direct impact on loyalty ($\beta = 0.389$; $p < 0.001$), whereas regulatory compliance had an indirect impact through brand image ($p < 0.05$) but no direct impact on loyalty ($p > 0.05$). These Findings imply that medical device sector in Indonesia should prioritize market-driven strategies which integrate service quality excellence and continuous product innovation, while also positioning regulatory compliance as credibility foundation to empower brand image and sustain customer loyalty.

Keywords: Market-Driven Strategy, Regulatory Compliance, Innovation, Service Quality, Brand Loyalty.
JEL Code: M31, O32, L15, I11

I.   Introduction

The healthcare sector plays a central role in improving public health and wellbeing. However, it also contributes significantly to environmental challenges, especially through greenhouse gas emissions and medical waste generation (Ishaq et al., 2024). The COVID-19 pandemic raised public awareness of health and cleanliness, which has led to significant expansion in the medical device business. Medical products are now essential to the hotel, industrial, and residential sectors and are no longer just found in healthcare facilities. Demand for disposable medical devices is predicted to increase long after the epidemic is finished due to

growing public awareness of the significance of self-defense, hygienic practices, and attempts to prevent infectious diseases (Khalifa et al., 2021; Xu et al., 2022).

In Indonesia, the development of the medical device market has been bolstered by government policies regarding the Domestic Component Level (TKDN) and mandatory certification of healthcare products. These policies create opportunities for local manufacturing industries to strengthen their position in national and global supply chains (Jakovljevic et al., 2021; Kristanti et al., 2024). As one of the emerging local manufacturer in disposable medical equipment product, PT Sumber Energy Industry (SEI) operates in a competitive environment characterized by standardized products, price-sensitive market, and a strong dependence on regulation and certification. These condition places SEI in a strategic position that reflects the general challenges faced by domestic medical device manufacturers in Indonesia.

SEI's situation as a producer of health commodity products underscores the urgency of changing the company's strategic orientation. Fierce price competition due to the influx of low-cost imports, increasingly complex regulatory demands, and limited product innovation are challenges that must be addressed. Without a strong market orientation, the company risks losing long-term competitiveness and struggling to build brand loyalty. Furthermore, Lolemo & Pandya (2025) found that studies conducted in a variety of settings agree that satisfaction is a necessary precondition for loyalty. In marketing literature, customer loyalty has been emphasized as a goal for businesses that operate in fiercely competitive situations. Comprehending the elements that impact client loyalty is crucial for revenue growth, positive word-of-mouth, and customer retention (Daulay et al., 2024). Customers who have strong emotional ties to a brand will not only purchase its goods but also attempt to persuade others to do the same (Wu et al., 2024).

Despite the many existing literature and studies on market-driven strategies and brand loyalty, prior studies largely focused on consumer goods and service industries, with limited empirical evidence from medical device manufacturing sector, especially in Indonesia. Regulatory compliance, service quality and product innovation are discussed as isolated factors, instead of integrated as a strategic mechanism influencing brand image and loyalty. Furthermore, the mediating role of brand image, linking regulatory compliance and innovation to brand loyalty remains underexplored in business-to-business healthcare context. This study aims to address how market orientation, brand image, and service quality can play key roles in enhancing brand loyalty and company performance. This approach is expected to not only provide strategic implications for PT Sumber Energy Industry but also contribute to the development of marketing strategies within the Indonesian medical device manufacturing industry more broadly.

II. Literature Review and Hypothesis Development

2.1. Market-Driven Strategy

A market-driven strategy is a strategic framework that bases managerial decision-making on the market, according to Cravens & Piercy (2009, p.86) Market orientation is defined as an organizational culture that prioritizes cross-functional collaboration to provide superior customer value, as well as a thorough awareness of consumer needs and competition dynamics. This idea is crucial since it stands in contrast to a production-driven strategy that only considers internal efficiency. Businesses that don't focus on the market run the danger of losing their sustained competitive edge. A market-driven strategy also heavily relies on product innovation. According to Cravens & Piercy (2009, p.236), innovation is a customer-focused process that encompasses everything from needs analysis and concept development to the introduction of new products. Businesses can differentiate themselves, improve their competitive position, and cultivate favorable customer attitudes by consistently innovating. Product innovation in the medical device sector promotes adherence to strict requirements while also improving brand attractiveness.

Meanwhile, according to Hendarwan (2023) the market-driven strategy focuses on dynamic shifts in the business environment; instead of depending on its own capabilities, it must recognize the changing needs of its clients, the competencies of its competitors, and swift and unpredictable changes in the business

environment. Before deciding on the strategy that the company will employ, managers of the organization must take the strategic step of identifying the business environment. Moreover, Both internal (inside-out) and external (outside-in) evaluations are essential for developing strategies, setting prices, making purchases, and fulfilling client orders. Enhanced market sensing, customer connection, channel bonding, customer problem-solving, and other abilities are possessed by market-driven organizations. Market-driven strategies increase perceived dependability and confidence in the medical device industry, which is important because of strict regulations and patient safety concerns. Businesses have a greater chance of influencing recurring business and long-term client loyalty when they precisely match product innovation and communication with clinical demands.

2.2. Service Quality

The SERVQUAL model, according to Parasuraman et al., (1988) consists of five components namely reliability, assurance, tangibles, empathy, and responsiveness, which explain the dimensions of service quality. A company's brand image is strengthened, customers' opinions of its professionalism are improved, and loyalty is eventually increased by providing high-quality service (Utomo et al., 2025).This is especially important in the medical device sector, where purchase decisions are heavily influenced by guarantee of availability and quality standards. Other issues to consider are regulatory compliance and certification. Companies can get a competitive edge by enhancing customer trust and sustainability commitment by incorporating circular economy principles into their service offering (Sah et al., 2025). Building on this concept, Cravens & Piercy (2009, pp.32-36) proposed that external legitimacy serves as the foundation for market trust. In the medical equipment business, ISO, CE certification, and the Ministry of Health's distribution permit not only ensure quality standards, but also boost brand confidence. Regulatory compliance can increase brand trust, which increases brand image and institutional customer loyalty. As a result, relevant theory holds that regulatory compliance, service quality, product innovation, and brand image are critical variables in developing brand loyalty. This line of reasoning lends support to the conceptual framework and ideas presented in this study. Despite SERVQUAL presenting an advantageous structure of the evaluation of service quality, the focus on operational attributes is unlikely to fully reflect the clinical efficacy, technical excellence, and compliance with the regulation that prevail in medical device purchasing option.

2.3. Product Innovation and Differentiation

The process of developing a set of noteworthy differences to distinguish the company's products from those of competitors is known as a product differentiation. The first market entry is a major objective for businesses that employ a differentiation approach. Good product quality and a focus on innovation as the company's driving force can yield advantages through differentiation strategy. Additionally, innovation is the only way businesses may boost performance and obtain a long-term competitive edge. Innovation is characterized by creative change-making and commercial value (Semuel et al., 2017). The term "product differentiation" refers to commodities that are becoming more and more distinct in contemporary marketplaces, even though there is still a lot of misunderstanding about what product differentiation is. The process of their differentiation is the primary characteristic that aids in defining the value attribute that marketing adds to commercial products. In a marketplace, product differentiation refers to how one company's goods or services can be distinguished from those of another company. The buyer can be informed of the distinctions between a company's product and those of other companies operating in the same environment by using any distinguishing characteristics, such as the label or the location of manufacture, sale, or consumption.(Muthoni Mwabu & Munyoki, 2021)

According to (Mauliano & Arimbawa, 2025) Customer loyalty is positively and significantly impacted by the product differentiation variable in the Jati Indah Furniture company. This suggests that Jati Indah Furniture's ability to differentiate its products from those of its rivals will have a greater impact on the growth

of client loyalty. Customer loyalty is positively and significantly impacted by the brand image variable in the Jati Indah Furniture company. In this study, the most important factor impacting consumer loyalty is the brand image variable. This indicates that customer loyalty to Jati Indah Furniture will increase in proportion to the strength, favorability, and uniqueness of the brand connections.

2.4.   Brand Loyalty

Incorporating brand trust as a critical component that influences attitudes and behavioral intentions in the Theory of Planned Behavior (TPB) might improve brand loyalty. Customers' opinions and their intents to act are influenced by brand trust, which ultimately affects brand loyalty. In developing economies, where cultural factors greatly influence consumer behavior, the growth of TPB is particularly important (Masud et al., 2024). It is undeniably important that brand loyalty is influenced by the components of market-driven strategy which work together. The orientation of the market can be used to obtain client information and analyze the other business' competitors. This relationship is essential specifically in medical industry due to the fact that medical demands will increase the regulatory compliance.(Muthoni Mwabu & Munyoki, 2021) Product re-establishment through innovation will ensure that the brand or product is viewed more favorably by consumers and will advance the brand's image in their eyes. They will be able to cultivate brand loyalty in this way (Tarmidi & Wijaya, 2023). Customer loyalty and trust are explained by brand benefits and attributes, as we all know. Customers' uncertainty and vulnerability are lessened by brand loyalty. Conversely, consumers who don't trust a brand are neither devoted to it nor to its business propositions. Brands are present in everyday life, and consumers develop a mental and behavioral bond with these units of meaning. As a result, consumers gradually develop a sense of trust and loyalty toward brands and organizations.(Cardoso et al., 2022)

2.5.   Hypothesis Formulation

H1: Regulatory compliance positively affects brand image.
H2: Regulatory compliance positively affects brand loyalty.
H3: Service quality strongly affects brand image.
H4: Service quality positively affects brand loyalty.
H5: Product innovation positively affects brand image.
H6: Product innovation positively affects brand loyalty.
H7: Brand image positively affects brand loyalty.
H8: Brand image mediates the effect of regulatory compliance and product innovation on brand loyalty.
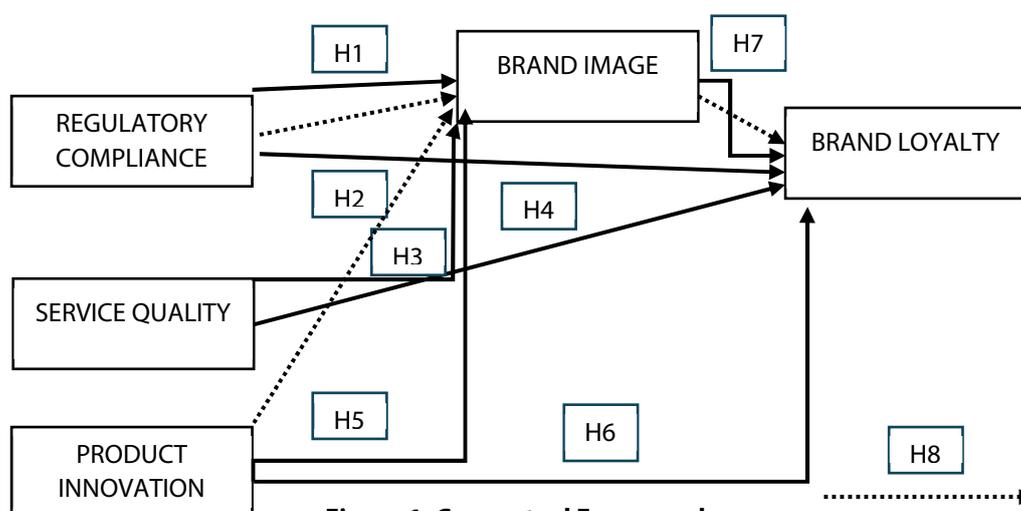
Figure 1. Conceptual Framework

In response to the research questions. We collected cross-sectional data from 120 respondents. In this work, simultaneous regression analysis has been performed to synchronize the findings of the structural equation models (SEM) and emphasize the study's robustness to strengthen the credibility and acceptability of the empirical analysis.

III.   Research Method

3.1.   Research Design

This study uses a quantitative explanatory research design under a positivist paradigm, which aims to test the causal relationships among regulatory compliance, service quality, product innovation, brand image and brand loyalty as proposed in the framework for the research. Measurement of the relationships among the variables were done using Structural Equation Modeling (SEM).

3.2.   Population and Sample

The population of this study consists of all active institutional customers, including hospitals and companies that utilize single-use healthcare products supplied by the company. A purposive sampling technique was employed, with the criterion that respondents must have completed at least one transaction, ensuring that all participants had prior experience with the products and services evaluated in the questionnaire. Exclusion criteria of no transaction prior is implemented to ensure respondents had direct exposure to the company's regulatory compliance, service quality and product performance. This ensures a context-specific result which primarily reflect the perceptions of institutional customers with prior transactional experience, with more relevant and valid response in exchange of a broader and more generalized outcome of a wider sample population.

The sample size determination followed the guideline proposed by Hair et al. (2010), which recommends a minimum of five to ten observations per indicator for studies employing Structural Equation Modeling (SEM). Based on this guideline, the final sample size of 120 respondents was deemed sufficient to meet the analytical requirements of the study and to support the robustness of the SEM analysis. This study adhered to basic research ethics principles. Participation in the survey was entirely voluntary, and respondents were informed of the purpose of the research prior to completing the questionnaire. To protect respondent privacy, no personal or institutional identifying information was collected during data gathering. Anonymity and confidentiality were maintained throughout the research process, and all data were used solely for academic purposes. The collected responses were analyzed in aggregate form, ensuring that individual participants or institutions could not be identified in the analysis or reporting of the results.

3.3.   Variables and Measurement

The questionnaire items for all variables were developed by the author based on conceptual definitions discussed in literature review, and adapted to the context of Indonesian medical device industry and institutional customers. Regulatory compliance is defined as the ability of the company to comply with regulation set by regulating ministry and global standards. It was constructed using indicators that reflect company's adherence to ISO 13485, ISO 9001, CE certification and licensing requirements issued by the Ministry of Health. Service quality is defined as the perception from the customer towards the company's service performance, measured using indicators corresponding to SERVQUAL dimensions, mainly reliability, assurance, tangibles, empathy and responsiveness. Product innovation and differentiation are operationally defined as the company's ability to develop and introduce new or improved products, measured using indicators that reflect product development activities, feature differentiation and speed of product introduction. Brand image is defined as the overall perception and association between customer and the

company's brand. This section was constructed using brand association, perceived quality and brand strength as basis. Brand loyalty is defined as customers' commitment to continue using the company's products. It was measured using indicators which may reflect repurchase intention, willingness to recommend and resistance to competitors. All indicators use a five-point Likert scale, ranging from strongly disagree (1) to strongly agree (5). Likert Scale is the main preference for this study due to its common and simple use in questionnaire and ease of response for participant. Content validity of the measurement instrument was based on the author's knowledge of management studies and practical understanding of the medical device industry. Content reliability was assessed using Cronbach's Alpha with a minimum threshold of 0.70 to concompany internal consistency.

3.4. Data Analysis

Data analysis includes descriptive statistics to summarize respondent profiles and responses, followed by Structural Equation Modeling (SEM) using SmartPLS software to test the proposed relationships among variables. SEM-PLS was chosen for its suitability for predictive and explanatory research and its effective applicability for moderate sample size. Data analyzed in the study consisted of primary quantitative data collected through structured questionnaires, with responses measured using five-point Likert Scale, producing data that reflect respondents's perception of regulatory complinace, service quality, product innovation, brand image and brand loyalty. Analysis followed a two stage procedure. First, measurement model was evaluated to assess indicator reliability, internal consistency reliability and construct validity. The structural model was evaluated to examine the relationships among the latent variables. Path coefficients and their significance levels were assessed to test the proposed hypotheses. The analysis focused on the magnitude and direction of the relationships between regulatory compliance, service quality, product innovation, brand image, and brand loyalty.

IV. Result and Discussion

4.1. SEM-PLS Analysis Results

The results of the SEM-PLS research yielded eight hypotheses on the impact of regulatory compliance, service quality, product innovation, and brand image on brand loyalty. The findings of this research demonstrated a fairly significant relationship between the structural model and the direction of the relationship, in accordance with existing theories. This demonstrates that Brand Image (BI) emerged as a construct with a major impact on Brand Loyalty. This is demonstrated by the highest route coefficient value ($\beta = 0.587$, $p < 0.001$). Furthermore, the existence of mediation analysis demonstrates that Brand Image plays a key role in mediation, particularly in the relationship between Regulatory Compliance (R) and Product Innovation (PI) and brand loyalty.

Table 1. Hypothesis Testing Results – Direct Effects

Hypothesis	Hypothesis Statement	β	p-value	Research Results
H1	Regulatory Compliance → Brand Image	0.255	<0.001	Supported (significant)
H2	Regulatory Compliance → Brand Loyalty	0.127	0.149	Not Supported (ns)
H3	Service Quality → Brand Image	0.503	<0.001	Supported (strong effect)
H4	Service Quality → Brand Loyalty	−0.170	0.042	Supported (significant, negative)
H5	Product Innovation → Brand Image	0.290	<0.001	Supported (significant)
H6	Product Innovation → Brand Loyalty	0.389	<0.001	Supported (significant)

| H7 | Brand Image → Brand Loyalty | 0.587 | <0.001 | Supported (strong effect) |
| H8 | Regulatory Compliance → Brand Image → Brand Loyalty | 0.148 | 0.001 | Supported (Partial Mediation) |

4.2. Evaluation of Regulatory and Certification Compliance in Building Customer Trust

Regulatory compliance is the process by which businesses ensure that their products, services, and operations comply with regulatory bodies' laws, rules, and standards. Certification, on the other hand, formally certifies that a product or procedure fulfills certain governmental or industry criteria. Regulatory compliance and certification are crucial for organizations in highly regulated sectors because they ensure that their products or services fulfill the required safety, quality, and performance standards(Arote et al., 2023). Cravens & Piercy (2009) highlighted that brand equity is the total added value that a brand possesses as a result of consumer loyalty, perceived quality, positive associations, and brand awareness. Increased consumer trust, a desire to spend more, and a larger chance of switching to competitors are all encouraged by strong brand equity. Although the usage of these strategies to improve brand equity was growing prior to 2018, the pandemic increased their significance and necessity (MohammadEbrahimzadeh et al., 2025). It can be said that employer brand equity is typically analyzed from the perspective of employee attraction and retention; however, little is known about how it interacts with service brand equity, what effect it has not only on employees but also on consumers' perceived service brand equity, their purchase and repurchase intentions, and their willingness to pay more (Ščiukauskė et al., 2024).

As a result, a company's brand image reflects its reputation, quality, and identity, all of which contribute to overall brand equity. A strong brand image has been shown to positively increase brand loyalty, where loyalty is defined as a customer's constant commitment to repurchase and resistance to rival offers (Oliver, 1999; Tahir et al., 2024). In business-to-business (B2B) situations, product dependability, service excellence, and corporate integrity are more important in shaping institutional buyer loyalty. This is consistent with assumptions 1 and 2, which state that regulatory and certification compliance improves brand image and so increases customer loyalty.

Hypothesis 1 (H1): Regulatory compliance positively affects brand image

The first hypothesis indicates that regulatory compliance has a positive effect on brand image. This is evident from the SEM-PLS analysis, which showed a significant path coefficient of $\beta = 0.255$ ($p < 0.001$). This means that H1 is supported. Regulatory compliance can influence Brand image which can lead to increased usage and purchase intentions (including repurchase intentions). The brand image can be described as the overall consumer in evaluating (Farrag, 2025). Patients are becoming more knowledgeable consumers who make deliberate choices about the services they get, which presents a significant challenge for the healthcare sector. This change in patient behavior highlights how crucial healthcare branding is becoming (Nagarajan, 2024). Furthermore, brand image represents the overall customer perception of a brand and is formed due to the experiences felt by customers while using the brand's product or service (Tahir et al., 2024).

In the healthcare industry contexts, companies must strategically portray regulatory compliance and certifications (such as promotional license, and standards of excellence) in the marketing and branding industry. Furthermore, they need to incorporate regulatory compliance into the customer experience hence the clients can experience their adherence through disclosure information, product consistency, and excellent services. Therefore, instead of performing as a distinct source of loyalty, regulatory compliance works as an instrument to cultivating perception.

Hypothesis 2 (H2): Regulatory Compliance does not directly affect Brand Loyalty

According to the test results, brand loyalty is not significantly impacted by regulatory compliance, with a coefficient value of β = 0.127 (p = 0.149). As a result, H2 is not directly supported. However, brand image has a large indirect influence (β = 0.148, p = 0.001), meaning that the overall impact of regulatory compliance on loyalty is still significant. According to Orazgaliyeva et al (2024), A company's ability to build competitive advantages grounded in client loyalty influenced by several factors such marketing complexity, customer satisfaction, trust, and awareness. Local pharmacies don't actively market their medications. Because of this, people frequently pick foreign equivalents because they believe they are more dependable and of higher quality than local medications. Regulatory compliance must be considered by industry actors as an important tool to establish brand loyalty, notably in the pharmaceutical and medical device industries. The priority should be on how those requirements transform into a trust-based competitive advantage rather than merely conforming to particularly in light of the perception that imported products are better than local products.

4.3. Analysis of Limited Customer-Centric Approaches in Developing Long-Term Relationships

In reality, most medical device manufacturing companies in Indonesia still employ a production-driven approach, focusing on production capacity and internal efficiency, rather than on actual consumer needs (Haag et al., 2023). Yet, strategic marketing literature emphasizes the importance of transforming into a market-driven company that possesses the ability to understand market dynamics (market sensing), build long-term relationships with customers (customer linking), and create unique value that is difficult for competitors to imitate. This is consistent with the findings of hypothesis 3 and 4, which reveal that service quality has a major impact on brand image and loyalty, implying that customer-centric practices play an important role in developing long-term relationship commitment. As a result, businesses' capacity to strengthen their brand image and establish long-lasting relationships with their customers may be limited due to ongoing reliance on production-driven approaches. The results indicated that enhancing relational value and developing long-term customer loyalty in the medical device sector necessitates an effort toward customer-driven methods, especially through continuous enhancements in service quality.

Hypothesis 3 (H3): Service quality strongly affects brand image

The third hypothesis states that service quality has a positive effect on brand image. The analysis results show a significant and strong relationship, with a coefficient of β = 0.503 (p < 0.001). H3 is supported. A company's relationship with customers may be impacted by the unpredictability of its product service quality (SQ), which might lead to customers responding to competitor offers. Increasing customer satisfaction and brand image are two benefits of improved service quality. Product features impact consumer satisfaction, and performance is evaluated in relation to pre-purchase expectations. Customer fulfilment and service quality have a positive relationship, making quality a useful indication of customer satisfaction. Any improvement in service quality has a favourable effect on customer satisfaction since the two are closely associated. While innovation in service quality is utilized to enhance service quality, higher product quality boosts customer satisfaction.

Service quality is a crucial component in the pharmaceutical sector, which includes the creation, manufacturing, and distribution of pharmaceuticals as well as medical services. Good service quality may lead to good attitudes, comfort, and trust in service providers. Service quality is a product or service that consumers anticipate to fulfill their wants and aspirations, in order to continually surpass customer expectations of the products or services they receive (Rahmi & Ridhaningsi, 2025). Since the industry's goal is to prevent, diagnose, and treat illnesses in order to improve public health (Feng, 2025)., providing excellent customer service directly helps to establish a positive brand image among customers. Therefore, maintaining a profitable business and building long-lasting client connections in the hospital sector depends on customer satisfaction (Almasarweh et al., 2024).

Hypothesis 4 (H4): Service quality positively affects brand loyalty.

The study found a substantial but negative correlation between service quality and brand loyalty (β = -0.170, p = 0.042). The indirect influence on brand image is significant (β = 0.296, p < 0.001). Thus, H4 is assisted by the mediation of brand image. These results align with earlier research demonstrating that patient loyalty is positively impacted by a number of aspects of service quality, including technical quality, non-prescription service, physical quality, relationship quality, and health and medication advice. Additionally, prior research has found differences in the quality of relationships between patients in the acute and chronic groups, indicating that the patient's condition may influence how service quality influences loyalty results (Darawong, 2025). Meanwhile according to Prasetyo et al., (2025) Customer loyalty was found to be most significantly predicted by customer satisfaction, highlighting the importance of this factor in building enduring connections

4.4. Implications of Limited Product Innovation for Market Differentiation and Brand Loyalty

Customer satisfaction benefits greatly from product innovation. Implementing innovation, such as cutting-edge technology, new business models, and personalized services, produces unique and efficient experiences, fulfilling the changing needs of clients. The Implications of Limited Product Innovation for Market Differentiation and Brand Loyalty study shows that innovation is critical for producing perceived added value for customers, whether through technical breakthroughs, product features, or more personalized services. This is consistent with research findings showing that product innovation has a positive and significant effect on brand image (H5) and brand loyalty (H6). Furthermore, brand image has been demonstrated to be a critical motivator of loyalty (H7), which may influence innovation's effect on loyalty through enhanced brand perception (H8). As a result, organizations that fail to innovate on a constant basis suffer issues in market distinctiveness, limiting customers from acquiring meaningful new experiences and, eventually, affecting their capacity to foster long-term loyalty. The author selected SEM-PLS method since it can manage predictive models with complicated relationships and mediating effects between implicit variables. The analysis of both direct and indirect relationships amongst product innovation, brand image, and brand loyalty (H5-H8) which are essential for the discussion on section 4.4. Therefore, the analysis showed that limited product innovation can influence long-term brand loyalty and market differentiation rely on a proper and trustworthy analytical method.

Hypothesis 5 (H5): Product innovation positively affects brand image.

The fifth hypothesis states that product innovation has a positive effect on brand image. The results show a significant effect (β = 0.290, p < 0.001), thus supporting H5. Innovation is the process of continually transforming different ideas into new products or processes for the firm's and stakeholders' advantage in relation to communication variables between the company and the environment. Meanwhile, product innovation may produce a variety of designs and product variations to enhance the product's value and advantages and make it more in line with consumer expectations. in order for product innovation to sustain the company's existence.(Febriyani et al., 2023) A brand image is a unique collection of visuals, names, phrases, characters, numbers, color schemes, and other features used in products and services commerce. Brand image significantly influences purchase decisions(Mangalindung & Hendayana, 2024). This finding is in line with the view that government policies often encourage innovation, particularly when regulatory intervention reduces reliance on direct customer–supplier interactions.

Hypothesis 6 (H6): Product innovation positively affects brand loyalty.

The results show that product innovation has a strong and significant effect on loyalty (β = 0.389, p < 0.001). Thus, H6 is supported. Additionally, social media zones enhance brand exposure through the usage of social communities, social publishing, and even a tiny amount of social commerce (Tabiat, 2022). These dynamics imply that client connection to a brand is strengthened by both innovation and successful digital engagement. Customers with high levels of trust are typically prepared to make short-term compromises because they think working with a business will provide substantial long-term advantages(Luthfitawati & Sutejo, 2025). However, Roberts (Roberts, 1999) emphasizes that businesses can maintain high profitability even with less frequent innovation, provided they are able to successfully evade the competitive constraints that usually undermine high returns. Loyalty, which refers to consumers' dedication and devotion to a certain brand, has been acknowledged as a critical component in the success of any company. It influences consumers' propensity to make more purchases, favorable word-of-mouth, and readiness to pay more for the brand. As a result, comprehending the factors that influence brand loyalty has emerged as a critical field of study in both academic and commercial domains. The subjective assessment of a product's degree of originality, or perceived product innovation, has become a key determinant of brand loyalty.(Guoha & Dellova, 2025)

Hypothesis 7 (H7): Brand image positively affects brand loyalty.

Brand image has the strongest influence on loyalty, with a path coefficient of β = 0.587 (p < 0.001). H7 is strongly supported. Brand image is an important aspect of a product that should be considered in addition to its features. Positive brand perception is a reflection of consumers' excitement and positive reactions to a business's products. According to Sudirjo et al. (2023) brand image serves as a synopsis of consumers' opinions and associations with a specific brand. Policymakers are urged to support compliance and efforts that improve customer loyalty and well-being, while businesses should foster a customer-centric culture that emphasizes comprehending and meeting customer demands in order to develop this relationship (Chen et al., 2024). According to this viewpoint, brand loyalty for frequently purchased brands has been demonstrated to be significantly and favorably influenced by popularity, knowledge, and familiarity, while knowledge and familiarity continue to be important drivers for less frequently purchased brands (Ewaldo Jader Pereira et al., 2021).

Hypothesis 8 (H8): Brand image mediates the effect of regulatory compliance and product innovation on brand loyalty.

H8 shows that, at a significance level of p = 0.001 and a mediation coefficient of 0.148, regulatory compliance affects brand loyalty through brand image. These findings suggest that brand image plays a role in mediating the relationship between brand loyalty and regulatory compliance. This implies that customers' perceptions of a company's brand are positively impacted by its compliance with regulations, which in turn boosts customer loyalty. However, regulatory compliance still has a direct impact on brand loyalty beyond brand image because of its partial mediation character. The utilization of purposive sampling strategy is relevant and analytical, especially since one of the aim of this study is to determine the Implications of Limited Product Innovation for Market Differentiation and Brand Loyalty. Respondents were selected according to specific criteria, including imdividuals and organizations with direct product application experience. These characteristics cannot be optimally represented through random sampling, since some respondents lack the knowledge and engagement necessary to assess brand image and loyalty in a meaningful way.

V.   Conclusion

It can be concluded that regulatory compliance, product innovation, and service quality all have a significant impact on market-driven strategic changes in the medical device business. These factors

collaborate to boost brand image and foster confidence among institutional customers. Product innovation boosts competitiveness in the face of shifting market demands during the epidemic, while adherence to standards like ISO, CE, and the Ministry of Health's distribution permit has been shown to enhance perceptions of quality and safety. Conversely, a company's professionalism and dependability are validated by consistent service quality, which increases customer loyalty by encouraging repeat purchases and decreasing the possibility of switching to competitors. Future research is recommended to deepen this current research by considering other relational and behavioral variables, such as customer trust, switching expenses, along with perceived risk, to better comprehend the mechanisms underpinning brand loyalty in regulated industry. Furthermore, Future research might also be used to examine service quality, product innovation, and brand image affect loyalty overtime. In addition, comparative research across healthcare sectors or between local and foreign enterprises may shed light on how contextual variables impact the role of customer-centric strategies in fostering long-term brand loyalty.

References

Almasarweh, M. S., Harb, A., Alnawaiseh, M. B., & Almajali, T. A. (2024). Beyond service excellence: Exploring brand image as the bridge between service quality and customer loyalty in nature tourist camps. Geojournal of Tourism and Geosites, 53(2), 725–735. https://doi.org/10.30892/gtg.53236-1248

Arote, K. S., Salade, D. A., & Patil, N. V. (2023). A brief review on regulatory affairs: Ensuring compliance, safety, and market access. International Journal in Pharmaceutical Sciences, 1, 22–30. https://doi.org/10.5281/zenodo.8397986

Cardoso, A., Gabriel, M., Figueiredo, J., Oliveira, I., Rêgo, R., Silva, R., Oliveira, M., & Meirinhos, G. (2022). Trust and loyalty in building the brand relationship with the customer: Empirical analysis in a retail chain in Northern Brazil. Journal of Open Innovation: Technology, Market, and Complexity, 8(3), 109. https://doi.org/10.3390/joitmc8030109

Chen, H., Akparep, J., Sulemana, I., & Osei, A. (2024). Advancing green innovations in pharmaceutical firms towards societal development: Nurturing customers' health and building loyalty. Environment, Development and Sustainability. https://doi.org/10.1007/s10668-024-05690-3

Cravens, D. W., & Piercy, N. F. (2009). Strategic marketing (9th ed.). McGraw-Hill Education.

Darawong, C. (2025). Examining the impact of hospital pharmacy service quality on patient loyalty in Thailand: The moderating role of illness condition. International Journal of Quality & Reliability Management. https://doi.org/10.1108/IJQRM-08-2024-0273

Daulay, R., Hafni, R., Nasution, S. M. A., Jufrizen, & Nasution, M. I. (2024). Determinants affecting trust, satisfaction, and loyalty: A case study of low-cost airlines in Indonesia. Innovative Marketing, 20(1), 101–112. https://doi.org/10.21511/im.20(1).2024.09

Ewaldo Jader Pereira, P., Marcelo Ardigó, C., & Flóres Limberger, P. (2021). Brand reputation and relationship with customer loyalty in the retail pharmacy sector: A case study. Review of Business Management, 23(3), 557–570. https://doi.org/10.7819/rbgn.v23i3.4120

Farrag, M. E. (2025). Investigating the effect of perceived healthcare products quality and brand image on brand usage moderated by brand trust. Journal of Advances in Economics and Business Studies, 2(1), 81–104. https://doi.org/10.21608/jaebs.2025.424641

Febriyani, Y., Sapta Putra, S., & Digdowiseiso, K. (2023). The influence of brand image, product innovation, and brand trust on the competitiveness of Wardah cosmetic products among students of the National University of Jakarta. Economic Journal, 12. http://ejournal.seaninstitute.or.id/index.php/Ekonomi

Feng, L. (2025). A study on the impact of corporate social responsibility performance on consumer purchase decisions: A case of the pharmaceutical industry. Business Administration and Economic Review.

Guoha, L., & Dellova, R. (2025). Perceived impact of product innovation on brand loyalty: A study of smartphone consumers in China. Diversitas Journal, 10(special_1). https://doi.org/10.48017/dj.v10ispecial_1.3151

Haag, K., Achtenhagen, L., & Grimm, J. (2023). Engaging with the category: Exploring family business longevity from a historical perspective. Family Business Review, 36(1), 84–118. https://doi.org/10.1177/08944865231154835

Hendarwan, D. (2023). Analysis of market-driven strategies to increase capabilities and performance advantages in business. Journal of Economic Empowerment Strategy, 6.

Ishaq, S., Hoang, T. G., Tanveer, U., Hoang, T.-H., & Truong, H. Q. (2024). Transformative capabilities of MedTech organizations in driving circularity in the healthcare industry: Insights from multiple cases. Journal of Cleaner Production, 446, 141370. https://doi.org/10.1016/j.jclepro.2024.141370

Jakovljevic, M., Wu, W., Merrick, J., Cerda, A., Varjacic, M., & Sugahara, T. (2021). Asian innovation in pharmaceutical and medical device industry – Beyond tomorrow. Journal of Medical Economics, 24(sup1), 42–50. https://doi.org/10.1080/13696998.2021.2013675

Khalifa, S. A. M., Swilam, M. M., El-Wahed, A. A. A., Du, M., El-Seedi, H. H. R., Kai, G., Masry, S. H. D., Abdel-Daim, M. M., Zou, X., Halabi, M. F., Alsharif, S. M., & El-Seedi, H. R. (2021). Beyond the pandemic: COVID-19 pandemic changed the face of life. International Journal of Environmental Research and Public Health, 18(11), 5645. https://doi.org/10.3390/ijerph18115645

Kristanti, I. G. A. M. I., Senastri, N. M. J., & Arjaya, I. M. (2024). Effectiveness of disposable medical device procurement in increasing the acceleration of the use of domestic products in RSUD Bali Mandara. Journal of Court and Justice, 3(1), 30–47. https://doi.org/10.56943/jcj.v3i1.485

Lolemo, S. E., & Pandya, H. B. (2025). Customer e-satisfaction as a mediator between e-service quality, brand image, and e-loyalty: Insights from Ethiopian digital banking technology. Journal of Digital Economy, 4, 1–15. https://doi.org/10.1016/j.jdec.2025.05.005

Luthfitawati, R., & Sutejo, B. (2025). Examining the influence of brand image and brand trust on customer satisfaction and loyalty: A study on Wardah cosmetics. Golden Ratio of Marketing and Applied Psychology of Business, 6(1), 179–192. https://doi.org/10.52970/grmapb.v6i1.1323

Mangalindung, G. H., & Hendayana, Y. (2024). The influence of product innovation, brand image, and brand trust on purchasing decisions (study literature). Dinasti International Journal of Management Science, 5(5).

Masud, A. Al, Ahmed, S., Kaisar, M. T., Hossain, B., Shimu, M., & Islam, M. F. (2024). Unveiling brand loyalty in emerging markets: Analyzing smartphone user preferences—Robustness of structural equation modeling and simultaneous equation modeling. Journal of Open Innovation: Technology, Market, and Complexity, 10(3), 100353. https://doi.org/10.1016/j.joitmc.2024.100353

Mauliano, I. R., & Arimbawa, P. A. P. (2025). The effects of product differentiation and brand image on customer loyalty. Jurnal Kewirausahaan dan Inovasi, 4(1), 23–34. https://doi.org/10.21776/jki.2025.04.1.03

MohammadEbrahimzadeh, S., Khajeheian, D., Arbatani, T. R., Labafi, S., & Sepasgozar, S. (2025). Sustainable knowledge-based enterprise products using AI-powered social media for enhancing brand equity: A scientometric review. Sustainability, 17(18). https://doi.org/10.3390/su17188427

Muthoni Mwabu, A., & Munyoki, J. (2021). A critical review of literature on product differentiation strategy and brand loyalty. Proceedings of the 3rd International Conference. http://ir.mksu.ac.ke/handle/123456780/8093

Nagarajan, D. V. (2024). Zoomers and healthcare choices: A study of mental processes of consumer decision-making in the digital age. Journal of Consumer Behaviour, 23(6), 2952–2974. https://doi.org/10.1002/cb.2382

Oliver, R. L. (1999). Whence consumer loyalty? Journal of Marketing, 63(Special Issue), 33–44. https://doi.org/10.2307/1252099

Orazgaliyeva, E., Abuzhalitova, A., Sokhatskaya, N., Smykova, M., & Kazybayeva, A. (2024). Trust as a critical driver of customer loyalty in the pharmaceutical market: A study of Kazakhstan. Regional Science Policy & Practice, 16(9), 100021. https://doi.org/10.1016/j.rspp.2024.100021

Parasuraman, A., Zeithaml, V. A., & Berry, L. L. (1988). SERVQUAL: A multiple-item scale for measuring consumer perceptions of service quality. Journal of Retailing, 64(1), 12–40.

Prasetyo, Y. T., Belmonte, Z. J. A., Esberto, E. M., Cahigas, M. M. L., Nadlifatin, R., & Gumasing, M. J. J. (2025). Cognitive perceptions and behavioral loyalty in telecommunication services: Integrating SERVQUAL and CSI in the Philippine context. Acta Psychologica, 259, Article 105298. https://doi.org/10.1016/j.actpsy.2025.105298

Rahmi, N. A., & Ridhaningsi, F. (2025). Service quality and innovation as drivers of customer loyalty. Golden Ratio of Marketing and Applied Psychology of Business, 6(1), 202–216. https://doi.org/10.52970/grmapb.v6i1.1327

Roberts, P. W. (1999). Product innovation, product-market competition and persistent profitability in the U.S. pharmaceutical industry. Strategic Management Journal, 20(7), 655–670. https://doi.org/10.1002/(SICI)1097-0266(199907)20:7<655::AID-SMJ44>3.0.CO;2-P

Sah, A. K., Hong, Y. M., & Huang, K. C. (2025). Enhancing brand value through circular economy service quality: The mediating roles of customer satisfaction, brand image, and customer loyalty. Sustainability, 17(3). https://doi.org/10.3390/su17031332

Ščiukauskė, I, Romeika, G., & Šarkiūnaitė, I. (2024). The consumers' perceptions of employer and service brand equity's: The exploratory and confirmatory factor analysis. Journal of Business Economics and Management, 25(1), 85–103. https://doi.org/10.3846/jbem.2024.20716

Semuel, H., Siagian, H., & Octavia, S. (2017). The effect of leadership and innovation on differentiation strategy and company performance. Procedia - Social and Behavioral Sciences, 237, 1152–1159. https://doi.org/10.1016/j.sbspro.2017.02.171

Sudirjo, F., Dewi, L. K. C., Elizabeth, Mustafa, F., & Santosa, S. (2023). Analysis of the influence of consumer behavior, product attributes, and brand image on purchasing decisions of pharmaceutical industry product consumers. JEMSI (Jurnal Ekonomi, Manajemen, dan Akuntansi), 9(6), 2432–2437. https://doi.org/10.35870/jemsi.v9i6.1648

Tabiat, A. (2022). The impact of digital marketing on sales performance: The case of Lebanese pharmaceutical companies. European Journal of Business and Management Research, 7(4), 349–355. https://doi.org/10.24018/ejbmr.2022.7.4.1600

Tahir, A. H., Adnan, M., & Saeed, Z. (2024). The impact of brand image on customer satisfaction and brand loyalty: A systematic literature review. Heliyon, 10(16), e36254. https://doi.org/10.1016/j.heliyon.2024.e36254

Tarmidi, D., & Wijaya, K. P. (2023). The impact of perceived value and product innovation toward brand loyalty on video premium application services. Jurnal Ekonomi, 12(1). http://ejournal.seaninstitute.or.id/index.php/Ekonomi

Utomo, S. B., Setiadi, B., Astuti, E. D., Wahyuningratna, R. N., Hendra, & Nusyirwan. (2025). The role of e-service quality and brand image on purchase intention of smartphone products. International Journal of Engineering, Science and Information Technology, 5(1), 290–296. https://doi.org/10.52088/ijesty.v5i1.714

Wu, J. C., Tsai, P. H., Tang, J. W., & Chen, C. J. (2024). Do store and brand attachments influence customer loyalty? Evidence from migrant workers in Taiwan. SAGE Open, 14(1). https://doi.org/10.1177/21582440241234794

Xu, J., Xu, X., Sun, K. S., Wu, D., Lam, T. P., & Zhou, X. (2022). Changes in residents' hygiene awareness and behaviors in public toilets before and during the COVID-19 pandemic in Hangzhou, China: A two-round cross-sectional study. BMC Public Health, 22(1), 1690. https://doi.org/10.1186/s12889-022-14114-8

Ye, C., & Zhang, J. (2025). How does customer concentration affect firm innovation in the Chinese pharmaceutical industry? Journal of the Knowledge Economy. https://doi.org/10.1007/s13132-025-02771-0