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Risk Management in the Pharmaceutical Industry Supply Chain at the Pharmaceutical Wholesaler Level

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ABSTRACT

The pharmaceutical industry in Indonesia faces several challenges in risk management, particularly in stakeholder management, which includes the government, healthcare providers, distributors, and the public. The complexity of regulations, market fluctuations, and changes in healthcare policies necessitate the implementation of effective risk management strategies in interactions with stakeholders. This study aims to analyze the implementation of risk management in stakeholder management within Indonesia's pharmaceutical industry, identify key risks that may impact business sustainability, and evaluate the mitigation approaches employed. A qualitative case study, incorporating in-depth interviews with key industry stakeholders, revealed that the primary risks include regulatory uncertainty, supply chain disruptions, and challenges in stakeholder communication and compliance. Effective mitigation strategies involve the adoption of adaptive compliance systems, strengthened communication and collaboration with regulators, and digitization of supply chains to enhance transparency and efficiency. This study underscores the importance of a risk-based approach in stakeholder management to ensure the sustainability and competitiveness of Indonesia's pharmaceutical industry.

Keywords: Risk management, stakeholder management, pharmaceutical industry, regulation, supply chain

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1. Introduction

The pharmaceutical industry plays a strategic role in the national healthcare system, particularly in ensuring the supply of high quality medicines and health products. In Indonesia, the pharmaceutical industry encounters a range of complex challenges, including strict regulations, fluctuations in raw material prices, and shifts in government policies that directly affect company operations. Additionally, the involvement of various stakeholders, such as the government, regulators, distributors, healthcare providers, and the public, adds another layer of complexity to risk management. Risk is any event that may arise in various activities due to uncertainty factors, which have the potential to hindering the achievement of a company's objectives (1–3). The potential losses resulting from risks can be very significant, making risk management very important. Risk Analysis is a process aimed at understanding aspects of risk, including its probability and impact, which can be carried out using qualitative and quantitative approaches to determine risk level (4,5). Impact refers to consequence of an event that affect achievement of the Company's objectives, in the form of an influence or effect that may arise from a given risk. Risk Probability (Probability Level) refers to the likelihood of a risk occurring. (6,7).

Risk management in stakeholder management became a crucial element in maintaining the sustainability and competitiveness of the pharmaceutical industry. Risks include regulatory uncertainty, supply chain disruptions, and challenges in communication and compliance with applicable regulations. Therefore, effective strategies are needed to identify, evaluate, and manage risks to improve business resilience and industry compliance with applicable standards.

Fostering relationships with stakeholders is a crucial element in ensuring a company's business sustainability, including in the pharmaceutical industry. Establishing strong stakeholder relationships is necessary for several key reasons. First, it enables companies to explore how stakeholders view and support their operations by providing insights into their interests, expectations, and concerns. Second, maintaining these relationships helps strengthen stakeholder perception and trust, which is vital for improving the company's reputation and influence. Third, stakeholder engagement is often a mandatory requirement in various compliance standards that companies must adhere to. Additionally, effective collaboration with stakeholders contributes to minimizing risks and resolving potential conflicts or problems. Most importantly, strong stakeholder relationships support the company in achieving its strategic goals and securing long-term business sustainability.

Stakeholders are refer to individuals or groups within society society party who have an interest or role related to a company or organization and are interconnected with and bound to each other (8). International Organization for Standardization (ISO) 2600 in its Guidance on Social Responsibility (2010) defines a stakeholder as an individual or group that has an interest in any decision or activity of an organization (9). Based on the definition, stakeholders can be identified using several keywords, including personal and institutional that are relevant to influencing, being influenced by, interests, financial, business, and regulation. There are three important aspects of stakeholder involvement: academic support, support

for business ethics and social responsibility, and financial support.

In general, corporate risk management is part of the concept of Quality Risk Management (QRM), as outlined in the International Council for Harmonisation – Quality Guideline 9 (ICH Q9) guidelines and Good Manufacturing Practices (CPOB) of 2024 annex XIII. These guidelines stated that the purpose of the quality risk management guidelines is to provide a systematic approach to quality risk management and to serve as an independent reference document, separate from other guidelines (10,11). Additionally, quality risk management guidelines also complement existing quality practices, requirements, standards and quality guidelines in the pharmaceutical industry. This study aims to analyze the implementation of risk management in stakeholder management within Indonesia's pharmaceutical industry, identify key risks that may impact business sustainability, and evaluate the mitigation approaches employed. According to World Health Organization (WHO) (2013) (12), the quality risk management process consists of several stages, including risk assessment, risk control, risk communication and risk review.

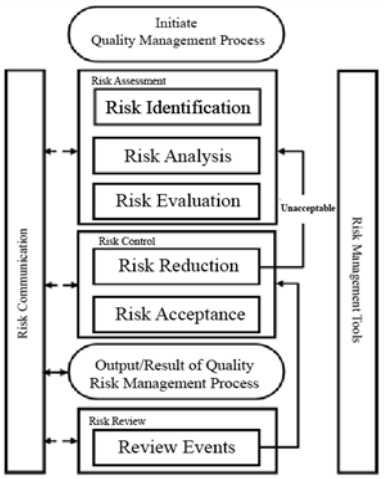


Figure 1. Quality Risk Management Process Flow in the Pharmaceutical Industry (Good Manufacturing Practices (CPOB) 2024, Annex 13) (10)

2. Method

The risk identification process was conducted using a qualitative approach based on case studies. We used the approximation method through the consensus, which is a qualitative approach to determining the probability and impact of risk. This method involves gathering a group of individuals to provide their opinions on the likelihood and impact of each identified risk. The participants must agree on the probability and impact level.

	Impact Level	Description
1	*Insignificant*	Very Small
2	*Minor*	Small
3	*Moderate*	Medium
4	*Major*	Big
5	*Catastrophic*	Very Big

Table 2. Preparation of Risk Profile & Risk Matrix Table

Goals/ Targets/ Strategic Issues	Reg. Number	Risk Event	Risk Event Group	Risk Category	Risk Agent		Time Horizon	Inherent Risk Value				Existing Control	Risk Mitigation	Residual Risk Value			
					Type	Description		Prob.	Impact	Impact Description	Risk Level			Prob.	Impact	Impact Description	Risk Level
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)	(15)	(16)	(17)	(18)

Description:

No	Column	Column Description
1	Goals/Targets/Strategic Issues	Filled with strategic goals/targets/issues
2	Registration Number	Number each identified risk
3	Risk event	Filled with potential events that could interfere with business activities
4	Risk Event Group	Filled with 15 (fifteen) groups of risk events that have been determined : 1. Stakeholder relations 2. Company reputation and image 3. Compliance failure 4. Changes in external policies 5. Supply chain disruptions 6. Export-Import Regulations 7. Pharmaceutical Distribution 8. Global Relations 9. Capital and Finance 10. Inspection and Supervision 11. Halal Regulations 12. Intellectual Property Rights (IPR) and Patents 13. Regulation and Public Policy 14. Public education 15. Country perception risk

5	Risk Category	Filled with 8 (eight) established categories: 1. Strategic Risk 2. Financial Risk 3. Operational Risk 4. Legal and Compliance Risk 5. Reputation Risk 6. Occupational Health and Safety (OHS) and Environmental Risks 7. Human Resources and Organizational Risk 8. Information Technology Risk
6	Type	Filled by selecting from 7 (seven) M + 1 (one) I types of risk causes: 1. Man (Human Resources), 2. Money, 3. Materials (Raw Materials), 4. Machines (Machines), 5. Method 6. Minute (Time), 7. Market and 8. Information
7	Description	Filled with a description of the identified risk causes according to the type of cause
8	Time Horizon	Divided into three: 1. Current = Risk can occur in less than 3 months 2. Medium = Risk can occur between 3-6 months 3. Emerging = Risk can occur between 6-12 months

9	Risk Probability	Filled with an assessment of the likelihood of a risk occurring based on the initially identified risk events **Level of Probability of Event:** 1. Almost Never Happens 2. Rarely Happens 3. May Happen 4. Often Happens 5. Almost Always Happens **Probability** 1. > 0% s.d. 20% 2. > 20% s.d. 40% 3. > 40% s.d. 60% 4. > 60% s.d. 80% 5. > 80% s.d. < 100%
10	Risk Impact	Filled with an assessment of the risk impacts that may arise if the identified risk event occurs. **Scale D:** / **Impact Description:** *1. Insignificant* — 1. Very Small *2. Minor* — 2. Small *3. Moderate* — 3. Medium *4. Major* — 4. Big *5. Catastrophic* — 5. Very Big
11	Risk Description	Filled with a description of the impact that can be quantified/described.
12	Risk Level	The risk position after being mapped into the risk matrix based on probability and impact data. 1. Insignificant = Small 2. Minor = Small 3. Moderate = Medium 4. Major = Large 5. Catastrophic = Very Large
13	Existing Control	Criteria: 1. Procedures already in place and have been implemented 2. Procedures already in place but have not been fully implemented 3. No procedures yet

14	Risk Management Plan	Filled with a plan of handling activities based on the identified risk events.
15	Risk Probability	Filled with the assessment of the likelihood of a risk occurring after risk management have been implemented
16	Risk Impact	Filled with the assessment of the risk impacts that may still arise after risk management/mitigation
17	Risk Description	Filled with the description of the impact (monetary value/other information), if the risk impact can be quantified/described.
18	Risk Level	Risk position after being mapped into a risk matrix based on probability residual risk probability and impact data

3. Result and Discussion

Risk Management is a method used by organizations/industries to control risks from all sources of risk in a company (2).

3.1 Overview of Stakeholder Risk Identification

Risk management is a strategic approach employed by organizations to control risks arising from various sources that could impact business objectives. In the context of Indonesia's pharmaceutical industry, stakeholder-related risks have become increasingly significant due to the complex regulatory landscape, dynamic public health policies, and the involvement of multiple actors including regulators, healthcare institutions, and the general public. This study identified key risks related to stakeholder management through a structured qualitative analysis and consensus-based evaluation process involving industry practitioners.

3.2 Risk Profile and Risk Matrix

A total of 15 strategic stakeholder-related risks were identified. These were analyzed based on their probability, impact, and mitigation measures. Table 2 summarizes the risk profile matrix, highlighting risk events, inherent and residual risk levels, and applied mitigation strategies.

Table 3. Risk Profile & *Risk Matrix*

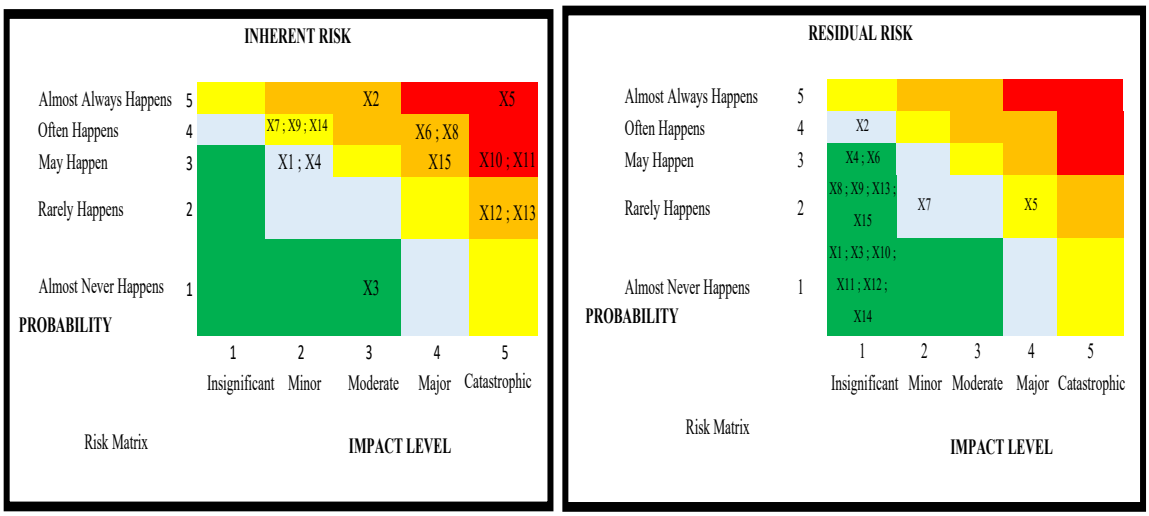
Goals/ Targets/ Strategic Issues	Reg. Number	Risk Event	Risk Event Group	Risk Category	Risk Agent		Time Horizon	Inherent Risk Value				Existing Control	Risk Mitigation	Residual Risk Value			
					Type	Description		Prob.	Impact	Impact Desc.	Risk Level			Prob.	Impact	Impact Desc.	Risk Level
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)	(15)	(16)	(17)	(18)
Enhance strategic partnerships with government and health institutions	001	Delays or failures in signing MoUs or cooperations	Delays or failures in signing MoUs or cooperations	Stakeholder relation	Reputation risk	Method	Regulatory changes, lack of effective communication	Emerging	3	2	Loss of business opportunities, decline in stakeholder trust	Minor	Procedures already in place but have not been fully implemented	Building proactive communication, monitoring regulatory changes, strengthening relationships with policymakers	1	1	Proactive communication and regulatory monitoring, ensure institutional relationships remain harmonious, accelerate cooperation signings, and maintain stakeholder trust.

Increase public confidence in pharmaceutical products	002	Negative issues or misinformation related to pharmaceutical products in the media	Negative issues or misinformation related to pharmaceutical products in the media	Company reputation and image	Reputation risk	Information	Lack of information control, attacks from competitors or health activists	Current	5	3	Declining public trust, decreased sales	Moderate	Procedures are in place and implemented	Communication strategy and crisis management, public education through credible media	4	1	The communication and public education strategy succeeded in maintaining the company's positive image, minimizing the impact of negative issues, and increasing public trust in pharmaceutical products.
Establish cooperation with international institutions for research and development	003	Failure to meet international cooperation standards or requirements	Failure to meet international cooperation standards or requirements	Compliance failure	Regulatory Risk	Method	Lack of understanding of international standards, global policy changes	Emerging	1	3	Loss of funding and collaboration opportunities, company image is affected	Moderate	Procedures are in place and implemented	International regulatory compliance training, establish a dedicated global cooperation team	1	1	Compliance with international standards enhances global collaboration opportunities, ensures research project sustainability, and builds a professional corporate image
Expanding market access through collaboration with BPJS Kesehatan.	004	Changes in BPJS financing schemes or policies that negatively impact the industry	Changes in BPJS financing schemes or policies that negatively impact the industry	Changes in external policies	Financial Risk	Method	Government policy instability, BPJS budget deficit	Emerging	3	1	Reduced profit margins, delayed claim payments	Minor	Procedures already in place but have not been fully implemented	Policy analysis and advocacy, market segment diversification	3	1	Good policy analysis and advocacy lead to more stable collaboration schemes, maintain profit margins, and enhance financial resilience
Enhancing the role of the pharmaceutical industry in national health resilience.	005	Dependence on imported raw materials affected by regulation and geopolitics	Dependence on imported raw materials affected by regulation and geopolitics	Supply chain disruption	Operational risk	Materials	Geopolitical crisis, changes in import regulations	Emerging	5	5	Production delays, potential increase in product prices	Catastrophic	Procedures are in place and implemented	Increasing the use of local raw materials, cooperation with alternative suppliers	2	4	Diversification of suppliers and utilization of local raw materials reduce the risk of supply chain disruptions, ensure production continuity, and strengthening national competitiveness.

Enhancing the competitiveness of pharmaceutical products in the global market	006	Export regulatory barriers due to policy changes or non-compliance with standards	Export regulatory barriers due to policy changes or non-compliance with standards	Export-Import Regulations	Regulation risk	Method	Policy changes in Customs, BPOM, Ministry of Industry, Ministry of Trade	Emerging	4	4	Products cannot enter target markets, losing export opportunities	Major	Procedures are in place and implemented	Export regulation monitoring, international compliance training, intensive communication with regulators	3	1	Understanding export regulations and standards compliance ensures smooth distribution of products to the global market, increasing export revenue and expanding market penetration.
Ensuring pharmaceutical distribution runs smoothly and according to standards	007	Distribution delays due to regulations or penalties from distribution institutions	Distribution delays due to regulations or penalties from distribution institutions	Pharmaceutical Distribution	Operational risk	Method	Strict distribution requirements from BPOM, Ministry of Health, or pharmacy associations	Emerging	4	2	Product not delivered on time, potential expiration, financial losses	Minor	Procedures are in place and implemented	Periodic distribution audits, collaboration with standardized distributors	2	2	Regular distribution audits and collaboration with trusted partners accelerate distribution, minimize expiration risks, and improve operational efficiency.
Strengthening international cooperation in the pharmaceutical industry	008	Unclear regulations on foreign investment and cooperation	Unclear regulations on foreign investment and cooperation	Global Relations	Regulatory and Reputation Risk	Method	Investment policy changes by BKPM, Ministry of Health, Ministry of Industry	Emerging	4	5	Decreased foreign investor interest, loss of development opportunities	Minor	Procedures are in place and implemented	Coordination with relevant regulators, pro-investment policy advocacy	2	1	Coordination with relevant regulators ensures international cooperation runs smoothly, increases foreign investment, and strengthens the company's position in the global market.
Ensure capital stability of the pharmaceutical industry	009	Difficulty in obtaining funding from financial institutions or financing Government-owned enterprises (BUMN)	Difficulty in obtaining funding from financial institutions or financing Government-owned enterprises (BUMN)	Capital and Finance	Financial risk	Money	Strict policies from the Ministry of Finance, Government State-Owned Enterprise, and other financing institutions	Emerging	4	2	Delay in business expansion, liquidity risk	Moderate	Procedures are in place and implemented	Diversification of funding sources, cooperation with strategic partners	2	1	Diversification of funding sources improves a company's liquidity, supports business expansion, and reduces dependence on a single funding source.
Meet the inspection and supervision standards of the pharmaceutical industry	010	Failures in audits and inspections by inspection agencies	Failures in audits and inspections by inspection agencies	Inspection and Supervision	Regulation risk	Method	Non-conformance with BPOM, Ministry of Health, or independent auditor standards	Emerging	3	5	Products recall from the market, fines and sanctions	Catastrophic	Procedures are in place and implemented	Strict regulatory compliance, training and audit simulations	1	1	Strict compliance with regulations and audit simulations enhance product quality, reduce the risk of sanctions, and ensure business sustainability

Ensuring halal certification of pharmaceutical products	011	Delay or failure to obtain halal certification	Delay or failure to obtain halal certification	Halal regulation	Compliance Risk	Method	Policy changes in BPJPH, LPPOM MUI, Kemenag	Emerging	3	5	Products cannot be marketed in certain segments, loss of trust from Muslim consumer	Catastrophic	Procedures are in place and implemented	Halal integration from R&D stage, close cooperation with halal authorities	1	1	Halal integration from the R&D stage accelerates the certification process, expands market segments, and enhances the trust of Muslim consumers
Protecting the Intellectual Property Rights (IPR) of pharmaceutical products	012	Patent disputes or IPR violations with legal impact	Patent disputes or Intellectual Property Rights violations with legal impact	Intellectual Property Rights (IPR) and Patents	Legal risk	Method	Imperfect registration at the DJKI or claims from third parties	Emerging	2	5	Loss of product exclusive rights, potential litigation	Catastrophic	Procedures are in place and implemented	Global IPR monitoring, strengthening patent protection from the early research stage	1	1	Global IPR monitoring and patent protection ensure product exclusivity, prevent litigation, and enhance the company's intellectual assets value
Influencing policies that support the pharmaceutical industry	013	Lack of understanding or support from the parliament in pharmaceutical policies	Lack of understanding or support from the parliament in pharmaceutical policies	Regulation and Public Policy	Regulatory and Political Risks	Information	Lack of communication between the industry, parliament, and stakeholders	Emerging	2	5	Unfavorable regulations for the industry, barriers to expansion	Catastrophic	Procedures are in place and implemented	Strategic engagement with the Parliament and policymakers, data-driven advocacy	2	1	strategic approach and data-driven advocacy create supportive policies, enhance regulatory stability, and strengthening the competitiveness of pharmaceutical industry.
Enhancing public trust in pharmaceutical products	014	Public unawareness of certain pharmaceutical products manufactured in Indonesia	Public unawareness of certain pharmaceutical products manufactured in Indonesia	Public education	Reputation Risk	Information	Lack of promotion and socialization in health care facilities and the general public	Emerging	4	2	Local products are less preferred, unoptimized domestic market potential	Minor	Procedures are in place and implemented	Promotion in healthcare facilities (faskes) and public education through credible media	1	1	Public education increases awareness and acceptance of local pharmaceutical products, strengthening the competitiveness of domestic products.
Strengthening international cooperation in the pharmaceutical industry	015	Potential partners' concerns about the credibility of the pharmaceutical industry in Indonesia	Potential partners' concerns about the credibility of the pharmaceutical industry in Indonesia	Country perception risk	Reputation risk	Information	Unstable political conditions and fraud cases tarnishing the industry's reputation.	Emerging	3	4	Loss of interest of strategic partners, risk of being abandoned by international partners	Major	Procedures are in place and implemented	Active participation in national, regional, and global forums helps build a positive image of Indonesia's pharmaceutical industry	2	1	Indonesia's positive image improved in the eyes of global partners, reducing partner concerns and opening up new strategic collaboration opportunities

To further visualize the risk levels, two risk matrices were developed — one reflecting the inherent risk (before mitigation) and one for the residual risk (after mitigation). The matrices help classify risks into five categories: Very Low, Low, Medium, High, and Very High, represented by colors (green to red).



The risk level resulting from the measurement of company risk is set in 5 (five) levels as follows:

Table 4. Risk Profile & *Risk Matrix*

RISK LEVEL	COLOUR
Very High	RED
High	ORANGE
Medium	YELLOW
Low	LIGHT BLUE
Very Low	GREEN

Table 3. Risk Level

Source : International Organization for Standardization (ISO) 31000:2018 – Risk Management Guidelines (2), and International Council for Harmonisation – Quality Guideline 9 (ICH Q9 Guidelines) (11).

The Company's risk management is conducted by considering the priority scale of the risk level. The determination of risk management strategies is based on the predetermined risk appetite, as follows:

Tabel . Risk Appetite

RISK LEVEL	Criteria
RED	**Very High Risk:** The risk is considered to have the potential to hinder the achievement of objectives and is recommended to be avoided, if this risk is still taken, immediate action must be implemented to mitigate it with special attention to detail, as it exceeds the Company's Risk Tolerance limit.
ORANGE	**High Risk:** The risk is considered to hinder the achievement of goals, and existing control mechanisms are insufficient to manage these risks. Mitigation measures are necessary to reduce the likelihood and/or impact of the risk.
YELLOW	**Medium Risk:** The risk is considered to have an impact on the objectives, but existing control mechanisms can still control it.
LIGHT BLUE	**Low Risk:** The risk is assessed as low and no mitigation is required.
GREEN	**Very Low Risk:** The risk is assessed as very low and no mitigation is required

Source : International Organization for Standardization (ISO) 31000:2018 – Risk Management Guidelines (2), and International Council for Harmonisation – Quality Guideline 9 (ICH Q9 Guidelines) (11).

3.3 Interpretation of Key Risk Levels

The analysis of the inherent risk matrix reveals several stakeholder-related risks that are positioned at the higher end of the risk spectrum. Among these, three risks stand out due to their high probability and severe impact: dependence on imported raw materials, audit and inspection failures, and delays or failures in obtaining halal certification.

The dependence on imported raw materials was assessed as having both a high probability and catastrophic impact. This risk is particularly critical given Indonesia's current reliance on foreign sources for active pharmaceutical ingredients (APIs). Disruptions caused by regulatory changes, geopolitical tensions, or global supply chain instability can lead to production delays and increased costs, thereby threatening the continuity of pharmaceutical manufacturing. The inherent vulnerability in this area reflects a structural challenge that requires long-term policy and industry-level intervention.

Similarly, failure to comply with audit and inspection requirements presents a high-impact risk. Regulatory agencies such as National Regulatory Authority (BPOM) and the Ministry of Health impose strict standards, and any non-conformity may result in sanctions, product recalls, or operational shutdowns. The data suggest that while procedures for compliance are often in place, they may not be consistently implemented or updated in accordance

with evolving guidelines.

The risk of delay or failure in halal certification is also significant, especially in a country where consumer demand for halal products is increasing. A failure in this area not only limits market access but also erodes consumer trust, particularly among Muslim populations. This risk is exacerbated by regulatory complexity and the need for timely coordination with institutions such as Indonesian Halal Product Assurance Organizing Agency (BPJPH) and Lembaga Pengkajian Pangan, Obat-obatan dan Kosmetika Majelis Ulama Indonesia (LPPOM MUI).

While these risks represent the most critical challenges, other risks such as negative media exposure, changes in BPJS Health policies, and difficulties in international cooperation were also identified as moderate to high in their potential impact. These findings emphasize that stakeholder-related risks are not only diverse but also interconnected across operational, reputational, and regulatory dimensions. Therefore, a multi-layered and anticipatory risk management approach is essential to ensure business continuity and industry resilience.

3.4 Discussion on Mitigation Strategies

The mitigation strategies identified in this study were designed to reduce both the likelihood and impact of key risks associated with stakeholder management in the Indonesian pharmaceutical industry. The findings show that while several inherent risks were initially assessed as moderate to catastrophic, the application of tailored mitigation actions successfully lowered many of them to low or very low residual risk levels. However, the effectiveness of these strategies warrants a deeper analysis.

One of the most prominent risks—dependence on imported raw materials—was categorized as catastrophic in both probability and impact. The proposed mitigation, which includes increasing the use of local raw materials and diversifying suppliers, is consistent with broader national strategies aimed at strengthening domestic production capabilities. However, the implementation of such strategies faces challenges such as limited availability of high-quality local Active Pharmaceutical Ingredients (APIs), gaps in production infrastructure, and price competitiveness. As emphasized by World Health Organization (WHO) (2013) and International Organization for Standardization (ISO) 31000, mitigation strategies must be not only technically sound but also contextually feasible and sustainable in the long term.

Similarly, risks related to regulatory compliance, such as failure during audits or delays in halal certification, were mitigated through structured training programs and process integration at the R&D stage. These measures are aligned with International Council for Harmonisation – Quality Guideline 9 (ICH Q9) recommendations for proactive risk prevention and are considered effective in embedding a culture of compliance. Nevertheless, these efforts must be continuously updated in response to changes in regulatory frameworks, especially given Indonesia's dynamic policy environment.

The risk of reputational damage due to misinformation in the media highlights the importance of stakeholder communication as a form of non-technical risk mitigation. While many companies have implemented communication strategies and public education campaigns, their impact is often difficult to quantify. Furthermore, trust-building efforts must go beyond

reactive statements and instead be based on long-term engagement with the public, healthcare professionals, and media channels. This is particularly critical in times of public health crises, where misinformation can spread rapidly and undermine confidence in pharmaceutical products.

Moreover, several mitigation actions depend heavily on inter-institutional collaboration, such as partnerships with government bodies and international organizations. For these strategies to be effective, companies must adopt a more strategic approach in building institutional relationships, engaging in policy advocacy, and aligning with national health objectives. The success of such approaches is not merely technical but also political and social, as it requires mutual trust, transparency, and alignment of interests.

In summary, while the identified mitigation strategies demonstrate a strong foundation in risk control theory, their success depends on implementation quality, contextual adaptability, and continuous evaluation. Future risk mitigation frameworks should integrate dynamic monitoring tools and stakeholder feedback mechanisms to ensure that residual risks remain within acceptable thresholds and to support long-term business sustainability.

3.5 Implications for Business Sustainability

Stakeholder-related risks are not only operational threats but also strategic concerns that affect the reputation, compliance posture, and financial resilience of pharmaceutical companies. The study underscores that effective stakeholder engagement, paired with robust risk control systems, plays a central role in enhancing long-term business sustainability. By aligning risk mitigation with stakeholder management practices, companies can safeguard their license to operate and build trust within the health ecosystem.

4. Conclusion

The pharmaceutical industry's stakeholder management encounter multiple risks that can impact business sustainability. From the pharmaceutical industry's business processes, 15 (fifteen) potential risks in stakeholder management have been identified. These risks were categorized as follows 5 risks fall under reputation risk, 5 risks fall under regulatory risk, 2 risks fall under financial risk, 2 risk fall under operational risk, 1 risk falls under compliance risk, 1 risk falls under legal risk,1 risk falls under political risk. Risk analysis revealed that the most critical stakeholder management risks, those with the highest risk level, including dependence on imported raw materials (vulnerable to regulatory and geopolitical factors), failure in audits and inspections by regulatory agencies, and delays or failures in obtaining halal certification. The recommended risk management to mitigate these high-priority risks such as increasing the use of local raw materials, establishing partnerships with alternative suppliers, ensuring strict compliance with regulations, providing training and simulations for halal audits integrated from the R&D stage, and establishing close cooperation with halal authorities.

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