REGULATION OF RISK-BASED BUSINESS LICENSING AND ITS RELATIONSHIP WITH SMALL TRADITIONAL MEDICINE BUSINESSES

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ABSTRACT

Risk-based business licensing is a government innovation designed to simplify the licensing process. The Traditional Medicine Small Business (TMSB) falls under this framework in the health sector, governed by Minister of Health Regulation No. 14 of 2021 and Minister of Industry Regulation No. 9 of 2021. However, these regulations assign different risk levels to TMSBs: "High Risk" by the Ministry of Health/NADFC and "Low Medium Risk" by the Ministry of Industry. This research analyzes the regulatory position of TMSB licensing, particularly in light of the Minister of Economic Affairs' letter No. PI.01/433/SES.M.EKON/06/2021, which concerns the Standard Classification of Indonesian Business Fields (SCIBF). The study employs a normative juridical approach, examining legal principles and statutory regulations related to TMSB licensing. Findings indicate a lack of synchronization between the risk levels set by different ministries, potentially leading to public health risks from unsafe pharmaceutical products. The research recommends a coordinated review involving the Capital Investment Coordinating Board, Ministry of Economic Affairs, Ministry of Health, Ministry of Industry, and National Agency of Drug and Food Control (NADFC) to harmonize TMSB licensing regulations and safeguard public health.

Keyword: *Risk-based business licensing, regulatory position, Traditional Medicine Small Business*

1. INTRODUCTION

Licensing serves as a policy instrument for the Government and Regional Governments (Pemda) to regulate and control negative externalities that may arise from social and economic activities. It also functions as a legal protection mechanism, ensuring the legitimacy of ownership or the conduct of specific activities. For licensing to be an effective control instrument, it must be grounded in clear, rational principles and articulated through government policies that provide a consistent framework for regulation and enforcement [1]. Without rationality and a clear policy design, licensing loses its effectiveness as an instrument to protect societal interests against actions driven by individual agendas. A well-structured licensing framework is essential to ensure that the regulatory process serves the broader public good, rather than merely enabling personal or commercial interests [2].

Given its crucial role in preventing market failure, the licensing function is clearly a regulatory responsibility that must be carried out by the government. Overly strict licensing requirements can drive economic activities into the informal sector, often referred to as the black market. On the other hand, excessively lenient licensing can lead to significant social costs, such as traffic congestion, environmental degradation, the proliferation of illegal products, and pollution resulting from unregulated market activities. Therefore, finding a balanced approach to licensing is essential to protect societal interests while fostering a healthy, regulated economy [3]. Risk-Based Business

Licensing Regulations in each sector typically encompass several key elements. These include the SCIBF code, which is relevant to the business activity, brand, and the businesses' name. The regulations outline the scope of activities covered, the risk parameters used to assess the associated risk, and the risk level assigned to the business activity. They also specify the business licensing requirements and processes, the time period for compliance, the validity period of the business license, and the authority responsible for issuing and overseeing the license [4].

In business operations, risks are inherent and refer to the potential for injury or loss arising from hazards, or the combination of the likelihood and consequences of such hazards. The risk level of business activities is central to the implementation of the risk-based approach (RBA). In this approach, the level of risk associated with a specific business activity dictates the degree of government oversight. Higher-risk activities are subject to stricter controls, more extensive permitting requirements, and increased inspections. Consequently, legal licensing documents for each business activity are designed to reflect and manage the associated risk level [5].

The principle of Risk-Based Business Licensing is "Trust but Verify." This approach shifts the traditional licensing concept from ex-ante, where requirements must be met before a license is granted, to ex-post, where verification occurs after the requirements are fulfilled. This means that businesses are initially trusted to comply with regulations, but their compliance is later verified through inspections and other forms of oversight [6]. This concept is particularly applicable to low-risk business activities or those with established standards. Once business actors begin operations in accordance with these standards, the government, as the regulatory authority, will verify their compliance through subsequent inspections and oversight [7]. Business permit applicants are provided with easier access to obtain legal authorization for their operations. However, post-permit supervision is crucial and must be conducted in an accountable and transparent manner to ensure ongoing compliance with regulations [8].

Business licensing services in the health sector are crucial to advancing health development, which is an integral part of national development rooted in Pancasila and the 1945 Constitution of the Republic of Indonesia. Health development aims to achieve the highest possible level of public health and necessitates clear, well-directed efforts to reach this goal. These licensing services play a pivotal role in ensuring that health development aligns with national objectives and contributes to the overall well-being of the Indonesian people [2].

Industries within the health sector typically fall into the high or medium-high risk-based business categories. This includes sectors such as the Traditional Medicine Raw Materials Industry for Humans and the Traditional Medicine Products Industry for Humans, due to the critical nature of safety and security in both the production and distribution of traditional medicine. According to a derivative of PP 5 of 2021 on the Implementation of Risk-Based Business Licensing in the health sector, the Ministry of Health of the Republic of Indonesia issued Minister of Health Regulation No. 14 of 2021 on April 1, 2021. This regulation specifies that the SCIBF 21022, which pertains to the Traditional Medicine Products Industry for Humans, classifies TMSB as having a "high level of risk."

In the implementation of risk-based licensing, a notable issue is the overlap of 140 SCIBF codes, as outlined in Attachment I of PP 5 of 2021 concerning the implementation of risk-based business licensing. This overlap involves two ministries/institutions: the Ministry of Health and the Ministry of Industry. One of the intersecting codes is SCIBF 21022, which pertains to the Industry of Traditional Medicinal Products for Humans, specifically TMSB. According to the Ministry of Health's regulation under Minister of Health Decree Number 14 of 2021, this sector is classified as "high risk." Conversely, the Ministry of Industry, under Indonesian Minister of Industry Decree No. 9 of 2021, assigns a "medium low" risk level to the production of traditional medicines for humans. This discrepancy highlights the need for alignment between different regulatory frameworks to address overlapping classifications effectively.

The differing assessments of risk levels between ministries will impact the stringency of the business licenses issued. Variations in risk classification affect regulatory oversight and the rigor of compliance requirements. This divergence also poses potential risks to patient and community safety, as inconsistent standards in the production of traditional medicines by TMSB facilities may lead to the distribution of substandard products. Ensuring alignment and consistency in risk assessments across institutions is crucial to safeguarding public health and maintaining regulatory efficacy [7].

To address the issue of intersecting SCIBF codes, the government has involved all relevant ministers and heads of sector institutions to coordinate and synchronize regulations across different sectors and ministries. This collaborative approach led to the issuance of a new policy via a letter from the Coordinating Ministry for Economic Affairs (Number PI.01/433/SES.M.EKON/06/2021) dated June 16, 2021. This policy outlines the handling of the 140 intersecting SCIBF codes, including SCIBF 21022. According to this letter, the Ministry of Industry is designated as the primary supporting institution, while the Ministry of Health and NADFC are also recognized as supporting institutions in this regulatory framework [4].

The lack of synchronization between regulations derived from PP 5 of 2021 concerning risk-based licensing, and the corresponding regulations from the Ministry of Industry and the Ministry of Health, has led to potential legal issues.

This disjunction affects the determination of the risk level for SCIBF 21022, specifically for the TMSB traditional medicine industry, and hampers the development of cohesive policies for addressing these issues. This inconsistency may lead to formal legal problems regarding TMSB licensing and substantive issues related to jurisdictional authority between the two ministries. Furthermore, if traditional medicine products from TMSB facilities, classified under a low-risk level, fail to meet quality and safety standards, there is a significant risk to patient safety and public health. Ensuring regulatory alignment and effective enforcement is crucial to mitigate these risks and safeguard the health and safety of the community.

The use of traditional medicine remains prevalent in urban areas, despite the availability of numerous health facilities and conventional medicines. Data from the NADFC over the past three years reveals a concerning trend in the number of cases involving traditional medicines containing illegal substances. In 2020, NADFC handled 31 such cases; in 2021, 53 cases; in 2022, 61 cases; and as of October 2023, 52 cases have been reported. This increasing number of cases indicates that some traditional medicine businesses are engaging in violations, highlighting the need for stricter regulation and oversight to ensure the safety and quality of these products. The presence of MC (Medicinal Chemicals) in traditional medicine poses significant health risks to consumers [9]. For instance, the addition of Sildenafil Citrate can lead to severe side effects, including loss of vision and hearing, chest pain, dizziness, facial swelling, stroke, heart attack, and even death. Similarly, the use of Dexamethasone, Phenylbutazone, and Paracetamol can result in growth disorders, osteoporosis, hormonal imbalances, hepatitis, kidney failure, and liver damage. Ephedrine and Pseudoephedrine can cause symptoms such as dizziness, headaches, nausea, nervousness, tremors, loss of appetite, stomach irritation, allergic reactions, and respiratory issues [6]. An initial study conducted by NADFC in collaboration with the Faculty of Medicine at Gadjah Mada University (UGM) in 2016 estimated the annual cost of illness related to kidney failure from consuming traditional medicines containing MC to range from IDR 562 million to IDR 200 billion. These findings highlight that some traditional medicine production facilities still produce products that compromise patient safety, underscoring the urgent need for stricter regulation and enforcement to protect public health [10].

The theoretical and formal legal issues surrounding traditional medicine have raised concerns about potential implementation problems in the field. These concerns have proven valid, as evidenced by a recent case reported to the NADFC on August 3, 2023. Japanese authorities informed NADFC of an incident involving 'Jamu Tea Black,' which was consumed by a 13-year-old child who subsequently experienced hormonal disorders. The product was found to contain dexamethasone, a substance that should not be present in traditional medicine. This case not only damaged Indonesia's reputation but also negatively impacted compliant traditional medicine companies.

The production and distribution of traditional medicines containing MC not only pose serious risks to public health but also create an unhealthy business climate and tarnish the reputation of Indonesian traditional medicine products globally, as seen in the recent incident in Japan. Unscrupulous actors exploit the public’s lack of awareness by adding MC to traditional medicines to maximize profits. The current ease of obtaining TMSB licensing, coupled with inadequate support and oversight from the Ministry of Health and NADFC, increases the risk of abuse by unethical business operators [11]. The limited guidance and supervision from government agencies, along with insufficient verification of pharmaceutical facilities and products by the Indonesian Ministry of Industry, contribute to these problems. Consequently, this lack of oversight impacts all levels of society, endangering those who use or receive traditional medicine products [12].

2. METHOD

This research employs a normative juridical approach with a qualitative methodology. The study begins with preliminary research aimed at gathering input for discussion and analysis, ensuring the reliability and accountability of the findings. The normative juridical method is used to seek truth through legal scientific logic by examining both primary and secondary data related to the issue at hand. This approach aims to describe and analyze legal materials to draw provisional conclusions regarding TMSB licensing, particularly in relation to the letter from the Coordinating Ministry and its legal standing in relation to the Regulations from the Ministry of Health and the Ministry of Industry. Secondary data sources for this research include statutory regulations, books, internet sites, and mass media. Specific legal materials analyzed include the 1945 Constitution, relevant statutory regulations, and the Regulation of the Head of the Indonesian National Agency of Drug and Food Control Number 31 of 2022 concerning technical guidelines for good traditional medicine manufacturing practices. Data will be examined through a literature study, with qualitative analysis of secondary data obtained from library research, involving the systematic organization of written legal materials.

3. RESULTS AND DISCUSSION

The formal legal authority of the Ministry of Health is outlined in Article 5 of the Minister of Health Regulation Number 5 of 2022, which pertains to the Organization and Work Procedures of the Ministry of Health. According to this regulation, the Minister of Health is responsible for formulating policies, implementing policies, providing technical guidance, supervising, and conducting evaluations. The Minister is supported by the Director General, who oversees development and supervision within the pharmaceutical sector through the Directorate General of Pharmacy and Medical Devices. Specifically, Article 138 of this regulation designates the Directorate of Pharmaceutical Production and Distribution as the entity responsible for the development and supervision of TMSB facilities.

Article 418, paragraph (10) of Law Number 17 of 2023 regarding Health stipulates that both the Central Government and Regional Governments are responsible for providing guidance related to Health Resources and Health Efforts. According to Minister of Health Regulation No. 14 of 2021, the Indonesian Ministry of Health's authority in the risk-based business licensing process includes the verification of TMSB licensing requirements. This authority is delegated to the Regional Government, specifically the Provincial Government. In alignment with Law Number 23 of 2014 concerning Government Affairs, the authority to grant TMSB permits is vested in the Provincial Government, which is executed by the Provincial Health Service.

A restrictive interpretation of the guidance and supervision of TMSB implementation suggests that these responsibilities lie with the permit issuer. However, a conflict arises because the Ministry of Industry, responsible for TMSB risk determination, has regulations that conflict with the aforementioned guidelines. This misalignment leads to overlapping authorities and potential laxity in licensing requirements, which could result in traditional medicines failing to meet safety and efficacy standards. The Ministry of Industry's designation as the K/L responsible for risk-based business licensing means that the Ministry of Health and its Provincial Health Service no longer have authority to verify TMSB licensing within the OSS RBA application system (pre-market). This shift impedes the Provincial Health Service's ability to access up-to-date information. Conversely, the Provincial Health Service retains its post-market development role as mandated by Law No. 23 of 2014 concerning Government Affairs. In summary, the authority to issue risk-based business permits for TMSB traditional medicines (pre-market) does not lie with the Indonesian Ministry of Health. However, the Provincial Health Service still retains its post-market development responsibilities in line with the law.

According to Article 193 of Minister of Industry Regulation No. 8 of 2023, the authority of the Indonesian Ministry of Industry's Inspectorate General encompasses several key responsibilities, including:

1. Annual Internal Audit Planning: Preparing and executing an annual internal audit plan, including identifying and updating data on all work units subject to supervision and required documents.
2. Compliance Audits: Conducting audits to ensure compliance with applicable regulations, provisions, and procedures.
3. Internal Control and Risk Management Evaluation: Testing and evaluating internal control and risk management systems in line with government policies.
4. Performance Audits: Ensuring efficiency, effectiveness, and economy in organizational business and operational processes, as well as evaluating programs and policies.
5. Consultancy Services: Providing advisory services without assuming management responsibilities.
6. Improvement Suggestions: Offering recommendations for improvements and objective information about supervised activities at all management levels.
7. Audit Reporting: Preparing and submitting audit reports to the Minister of Industry and relevant audit bodies.
8. Follow-up Monitoring: Monitoring, analyzing, and reporting on the implementation of recommended improvements.
9. Quality Evaluation Program: Developing programs to evaluate the quality of internal control activities.
10. Public Complaint Follow-up: Taking actions based on the results of public complaints.
11. Bureaucratic Reform: Actively contributing to and promoting bureaucratic reform within the Ministry of Industry.
12. Special Inspections: Conducting special inspections as necessary.
13. Peer Reviews: Performing internal and external peer reviews.
14. Special Assignments: Undertaking special assignments mandated by the Minister provided they do not compromise independence.

The authority of the Indonesian Ministry of Industry in risk-based business licensing is well-defined. Specifically, it holds access rights to the OSS RBA application for risk-based business licensing related to traditional medicine

production. According to Minister of Industry Regulation No. 9 of 2021, TMSB are classified under the medium-risk category. With the issuance of the Business Identification Number (BIN) and the completion of the Self-Assessment (SA) automatically through the OSS application, business actors are presented with opportunities to operate more easily. However, this process also increases the risk that traditional medicine production may not adhere to established quality, safety, and efficacy standards.

NADFC's sampling data reveals that traditional medicines failing to meet safety and quality standards are found even in facilities that possess distribution permits and CPOTB certificates. This concern is heightened by the ease of issuing TMSB permits, which could lead to an increase in traditional medicines that do not meet quality and safety standards. To address this, TMSB business actors with existing permits should include a commitment statement to comply with CPOTB requirements and then obtain the PBUMKU operational permit for traditional medicine production. This process involves Indonesian NADFC authority. The Ministry of Industry's role in pre-market and post-market guidance does not focus on quality, safety, or efficacy. According to Minister of Industry Regulation No. 8 of 2023, the Ministry's guidance is limited to administrative and industrial requirements, without overseeing safety, quality, and benefit standards. This delineates the Ministry of Industry's authority to licensing administration and industrial compliance, while the responsibility for ensuring safety, quality, and benefits remains with Indonesian NADFC.

The NADFC is instrumental in safeguarding public health by regulating the quality and safety of medicines and food products. Its primary role is to ensure that products meet rigorous standards before they are allowed into the market. This involves a comprehensive pre-market evaluation process where NADFC assesses the safety, efficacy, and quality of products. Before a product can be circulated, it must undergo this thorough examination to confirm that it is both safe for consumption and effective for its intended purpose.

In addition to pre-market evaluation, NADFC is responsible for ongoing regulatory oversight. This includes issuing licenses and certifications to ensure that products and production facilities adhere to government standards. The agency enforces these regulations to maintain high quality and safety standards throughout the lifecycle of the product. Post-market surveillance is another critical aspect of NADFC's work. The agency monitors products even after they have been released into the market. This involves reviewing reports of adverse effects and conducting market inspections to ensure that products continue to meet safety and quality requirements. When NADFC identifies products that do not comply with these standards, it has the authority to take enforcement actions. These actions can range from recalling products to issuing warnings or imposing penalties on non-compliant manufacturers or distributors. Moreover, NADFC plays a significant role in public education by raising awareness about safe practices and potential risks associated with medicines and food products. This educational effort helps consumers make informed decisions and recognize potentially hazardous products. Through these comprehensive measures, NADFC helps prevent the distribution of unsafe or ineffective products, thus ensuring that medicines and food available to the public are safe, effective, and of high quality. This proactive approach is essential for protecting public health and maintaining consumer trust in the safety of the products they use.

Supervision of medicines and food products during their circulation is a critical aspect of ensuring public safety and compliance with established standards. This supervision encompasses various stages, including pre-market and post-market phases. Before a product, such as traditional medicine, can enter the market, it must undergo rigorous checks. NADFC is responsible for overseeing this process to ensure that all products meet the required safety, efficacy, and quality standards. This includes verifying that production facilities comply with Good Manufacturing Practices (GMP) and that distribution permits are in place.

Given that traditional medicines classified under the medium low-risk category, such as those requiring only NIB and Self-Assessment (SA), may not undergo as stringent pre-market scrutiny, NADFC's role becomes even more crucial during the post-market phase. The regulatory focus shifts to ongoing monitoring and enforcement to prevent any potential lapses in safety and quality. In this context, NADFC must enhance its oversight of production facilities classified as low and medium low risk. There is a significant risk that some business actors might prioritize expediency over compliance, potentially bypassing essential aspects of GMP and operating without valid distribution permits. Such practices could lead to the circulation of unsafe traditional medicines, posing a serious risk to public health. To mitigate these risks, NADFC's supervision must include:

1. Ongoing Compliance Checks: Regular inspections of production facilities to ensure adherence to CPOTB standards and to verify that distribution permits are in place.
2. Enforcement Actions: Implementing measures to address non-compliance, such as product recalls or penalties for unauthorized distribution practices.
3. Sampling and Testing: Conducting market surveillance by sampling and testing traditional medicine products to confirm their compliance with safety and quality standards.

4. Public Education: Increasing efforts in educating the community about the dangers associated with traditional medicines containing unauthorized substances. This involves raising awareness among both consumers and business operators about the risks of using or producing such products.
5. Guidance and Support: Providing ongoing guidance and support to business operators to ensure they understand and meet regulatory requirements.

Through these measures, NADFC aims to uphold high standards for traditional medicines, ensuring that they are both safe and effective for public use. This comprehensive approach helps maintain public health and safety, while also safeguarding the integrity of the traditional medicine market.

To address the issue of intersecting CPOTB codes, such as CPOTB 21022 for traditional medicine production, it is crucial to follow a structured approach. The process begins with a thorough examination of the relevant regulations and ministerial decrees. This involves analyzing Government Regulation No. 5 of 2021, which provides the framework for risk-based business licensing. By understanding its guidelines and principles, we can identify how responsibilities are assigned for various SCIBF codes, including those that overlap.

Next, a review of Minister of Health Regulation No. 14 of 2021 is necessary. This regulation specifies the standards for business activities and products within the health sector. It is important to assess how this regulation classifies the risk levels associated with traditional medicine and the role of the Ministry of Health in overseeing these activities. Similarly, Minister of Industry Regulation No. 9 of 2021 must be examined. This regulation sets standards for business activities and products in the industrial sector, including traditional medicines. Understanding its approach to risk classification and the responsibilities assigned to the Ministry of Industry is crucial for resolving overlaps.

A material test should be conducted to ensure that the regulations align with the actual risk classifications and responsibilities of each ministry or institution. This involves comparing how each regulation determines risk levels and verifying whether they are consistent or conflicting. Clarifying the roles of the Ministry of Health and the Ministry of Industry in relation to SCIBF 21022 is essential for resolving overlaps and ensuring clear responsibilities.

Coordination among relevant stakeholders is also crucial. This includes the Investment Coordinating Board (ICB), the Coordinating Minister for Economic Affairs, the Ministry of Industry, the Ministry of Health, the NADFC, business actors, and local authorities such as governors and regents/mayors. Engaging these parties in discussions and aligning on how to manage intersecting SCIBF codes will help in developing a unified approach.

Following these discussions, new guidelines or amendments to existing regulations should be drafted and issued. These revised guidelines should address the identified issues and provide a clear framework for managing intersecting SCIBF codes. It is important to implement the revised framework effectively and continuously monitor its impact. Regular reviews will help ensure that the new guidelines are effective in regulating traditional medicine production and resolving the complexities associated with SCIBF overlaps. This approach will safeguard public health while providing clarity and consistency in the licensing process.

The reduced authority of the Ministry of Health, Provincial Health Service, and NADFC in the licensing process for traditional medicine production through the OSS RBA platform has significantly impacted the effectiveness of TMSB (Small Traditional Medicine Enterprises) development and supervision. This reduction in authority has created challenges in several key areas:

Firstly, the difficulty in accessing and updating the latest data on TMSB facilities has become a major obstacle. The Ministry of Health, Provincial Health Services, and NADFC traditionally played crucial roles in collecting and managing data related to traditional medicine facilities. With their reduced authority and limited access to the OSS RBA platform, these agencies face challenges in obtaining accurate and current information about TMSB operations. This data gap hampers their ability to monitor compliance effectively and ensure that TMSB facilities adhere to safety, quality, and regulatory standards.

Secondly, the integration of TMSB data with the OSS RBA system, which involves coordination with various ministries and institutions, has become problematic. The OSS RBA platform is designed to streamline and centralize business licensing processes, but the lack of updated data from TMSB facilities undermines the effectiveness of this system. The integration challenges prevent seamless coordination between the Ministry of Health, Ministry of Industry, NADFC, and other relevant authorities, affecting the overall efficiency of the licensing and supervision process. As a result, the guidance and supervision of TMSB facilities are not as effective as they could be. The reduced authority and limited access to data hinder the ability of these agencies to provide comprehensive oversight, enforce compliance, and implement effective measures to address any issues within the TMSB sector. This lack of synergy among the various agencies responsible for TMSB regulation impacts the quality and safety of traditional medicines, potentially leading to regulatory gaps and risks to public health.

To address these issues, it is crucial to enhance the integration and data-sharing mechanisms between the OSS RBA platform and relevant regulatory bodies. Strengthening collaboration among the Ministry of Health, Provincial Health Services, NADFC, and other stakeholders can improve data accuracy, facilitate more effective supervision, and ensure that TMSB facilities operate in compliance with established standards. Additionally, reviewing and potentially revising the regulatory framework to better align with current practices and challenges may be necessary to enhance the overall effectiveness of TMSB development and supervision.

To mitigate the potential legal issues associated with traditional medicines not meeting safety, quality, and efficacy standards, which could adversely affect public health and patient safety, it is essential to address several key areas:

Firstly, synchronizing the risk classification of traditional medicine production to a high-risk level is crucial. This involves adjusting the risk levels across relevant regulations and guidelines to ensure consistency and alignment with safety, quality, and efficacy standards. By categorizing traditional medicines as high risk, the licensing requirements for TMSB (Small Traditional Medicine Enterprises) should prioritize stringent standards for safety, quality, and efficacy, rather than focusing solely on ease of business licensing.

Secondly, enhancing the oversight of business licensing processes is necessary. This involves integrating rigorous safety and quality assessments into the TMSB licensing requirements to ensure that traditional medicines meet established standards before they reach the market. By doing so, the risk of non-compliant products can be reduced, thereby protecting public health.

Additionally, implementing robust Information, Education, and Communication (IEC) strategies is vital. Empowering both business actors and consumers through education and awareness campaigns about the dangers of traditional medicines containing Medicinal Chemical (MC) can help prevent the use of unsafe products. These campaigns should focus on informing the public about the risks associated with MC in traditional medicines and educating business operators on compliance with regulatory standards.

Moreover, involving all relevant ministries and institutions in the synchronization process ensures that regulatory measures are comprehensive and effectively address potential risks. Collaboration among the Ministry of Health, Ministry of Industry, NADFC, and other relevant bodies can facilitate a more coordinated approach to risk management and regulatory enforcement.

In summary, to address legal problems and safeguard public health, it is essential to:

1. Synchronize risk classifications to reflect high-risk levels.
2. Prioritize safety, quality, and efficacy in business licensing requirements.
3. Enhance IEC efforts to educate both business actors and consumers.
4. Foster coordination among relevant ministries and institutions to ensure comprehensive oversight and regulation.

4. CONCLUSIONS

The letter from the Coordinating Ministry for Economic Affairs (Number I.01/433/SES.M.EKON/06/2021) does not hold statutory weight like the Minister of Health Regulation No. 14 of 2021 and the Ministry of Industry Regulation No. 9 of 2021, which are binding and legally recognized. However, these two regulations have led to conflicting classifications due to differing scopes—health and industrial—which has caused inconsistencies in risk assessment for traditional medicine production. The principles guiding these regulations should align to avoid conflicts, but their current differences create legal ambiguity and regulatory gaps. This can impact the effectiveness of licensing and supervision, leading to potential risks to public health. To resolve these issues, it is crucial to synchronize the risk classifications between the regulations, enhance coordination among relevant ministries, and review the regulations to align them and ensure comprehensive oversight.

The authority of the Indonesian Ministry of Health, specifically the Provincial Health Service, in risk-based business licensing is limited to guiding and supervising the implementation of licenses rather than verifying OSS RBA applications. This role is outlined under Law No. 23 of 2014 concerning Government Affairs. In contrast, the Ministry of Industry is responsible for verifying TMSB business permits and overseeing the industrial sector related to TMSBs. Meanwhile, NADFC acts as the verifier for commitments related to GTMMP (Good Traditional Medicine Manufacturing Practices) and distribution permits for traditional medicines. NADFC also handles guidance and supervision during the fulfillment of GTMMP requirements and distribution permits, as well as overseeing production activities once TMSB permits are in effect.

The potential risks arising from Risk-Based Business Licensing, as outlined in the Letter from the Coordinating Minister for Economic Affairs, include significant threats to public safety. The classification of SMTB as low risk can lead to the production of traditional medicines that fail to meet essential safety, quality, and efficacy standards.

This oversight jeopardizes public health and the safety of individuals consuming these products, potentially resulting in harmful health outcomes.

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