International Conference Restructuring and Transforming Law 2026
Volume 5, Issue 1, July 2026
e-ISSN :2963-931X
icrtlaw@ums.ac.id

Normative Analysis of Traditional Medicine Industry Licensing Violations in Cases of Illegal Herbal Products based on Statutory Regulations

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Abstract

The development of the traditional medicine industry in Indonesia has experienced significant growth in line with the increasing public interest in herbal products, which are perceived as more natural and safer; however, such growth has not always been accompanied by compliance with licensing regulations, as evidenced by the persistence of practices such as production without marketing authorization, the use of fictitious marketing authorization numbers, and the mixing of pharmaceutical chemical substances into traditional medicine products. This research employs a normative juridical legal research method with a statutory approach, analyzing relevant laws and regulations, legal doctrines, and scientific literature related to business licensing and the regulation of the traditional medicine industry. The novelty of this study lies in the analysis of the legal position of KBLI 21022 as the basis of legal standing for the traditional medicine industry within the risk-based business licensing system, as well as its relation to violations involving fictitious marketing authorization numbers and the mixing of pharmaceutical chemical substances. The results indicate that KBLI 21022 has a constitutive role in determining the operational legality of the traditional medicine industry, serving as the basis for identifying business activities, determining risk levels, and establishing obligations such as fulfilling the Business Identification Number, Standard Certificate, production permits, and Marketing Authorization Number; moreover, Law Number 17 of 2023 concerning Health stipulates that production without a Marketing Authorization Number, the use of fictitious authorization numbers, and the mixing of pharmaceutical chemical substances constitute serious violations subject to administrative and criminal sanctions, with BPOM playing a central role in supervision and enforcement to ensure public health protection. Conclusion: Thus, the regulatory framework emphasizes the importance of compliance with risk-based licensing under KBLI 21022 and reinforces strict legal consequences for violations as part of safeguarding public health and ensuring legal certainty in the traditional medicine industry.

Keywords: KBLI 21022; risk-based licensing; traditional medicine; Marketing Authorization Number

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INTRODUCTION

The development of the traditional medicine industry in Indonesia has shown significant growth in recent years. People are increasingly choosing herbal products as alternative treatments because they are considered safer, more natural, and in accordance with cultural traditions (1). This condition has encouraged the growth of business actors in the traditional medicine sector. However, this growth has not been fully accompanied by compliance with applicable licensing regulations (2). This gap between the rapid development of the industry and legal obligations has given rise to various problems in the production and distribution of traditional medicines in Indonesia. Indonesia actually has a fairly comprehensive business licensing system, including the grouping of business fields through the Indonesian Standard Classification of Business Fields (hereinafter referred to as KBLI), where the traditional medicine industry is listed in KBLI 21022, which includes the processing and production of herbal medicines, traditional medicines, and herbal supplements. KBLI not only functions as an administrative code, but also provides a legal basis for business actors in carrying out production activities, so that every industry player is required to align their activities with these provisions to obtain full legality as a traditional medicine industry (3).

Guarantees for public safety and security have a constitutional basis as stated in Article 28H Paragraph (1) of the Constitution of the Republic of Indonesia, which states that everyone has the right to obtain a good and healthy living environment and health services. This provision indicates the state's obligation to ensure that all health products circulating in the community, including traditional medicines, meet adequate safety, quality, and benefit standards. Within the national regulatory framework, the traditional medicine industry is also categorized as a high-risk business in the risk-based business licensing system, so that business actors are required to fulfill various requirements such as production standard certification, fulfillment of production facilities in accordance with regulations, and ownership of a Distribution Permit Number (hereinafter referred to as NIE) before the product is marketed to the public (4). This regulation reflects the existence of an ideal norm, or *das sollen*, which places the protection of public health as the highest priority within the traditional medicine industry. This regulation also emphasizes that traditional medicine production activities are not only concerned with economic interests but also involve legal and social responsibilities regarding consumer safety.

However, these normative conditions have not been fully realized in practice in the field. Various news reports and monitoring reports indicate that herbal products are still being found circulating without official permits, the use of fictitious NIEs, and the mixing of chemical medicinal substances (hereinafter referred to as BKO) which should not be permitted in traditional medicines (5). This phenomenon shows a gap between ideal legal provisions and the reality of the practice of production and distribution of traditional medicines in society or what is known as the condition *das sein*. From a business ethics perspective, this practice not only violates the provisions of laws and regulations but also contradicts moral principles that require business actors not to cause harm to consumers (6). The values in Islamic law also provide a consistent foundation through the principle*al-hifz al-nafs*and rules*neither good nor bad.*which emphasizes the prohibition of causing harm to oneself or others (7). Therefore, compliance with traditional medicine industry permits is not merely an administrative obligation, but is a form of legal and moral responsibility in carrying out business activities that are directly related to public health.

The facts of these violations are evident in various cases of recalls of illegal herbal products by supervisory authorities, including the discovery of products containing hazardous chemicals and using fictitious NIEs (8). This situation shows that violations do not only occur in small, informal businesses, but can also involve industries that already have extensive distribution networks. In academic studies, research on licensing of traditional medicine industries has actually been conducted previously, particularly those that highlight aspects of supervision, consumer protection, and the responsibilities of business actors (9). However, most of these studies still focus on aspects of administrative supervision or product safety in general, while discussions regarding the legal status of licensing of traditional medicine industries within the framework of risk-based business licensing and its relationship to violations of the use of NIEs are still relatively limited. This condition indicates the literature gap which opens up space for further study regarding the relationship between the licensing system, forms of violations, and law enforcement mechanisms in the traditional medicine industry.

Based on this description, this research has novelty (*novelty*) in normatively analyzing the legal status of traditional medicine industry licensing in the risk-based business licensing system and examining the forms of violations that occur in the practice of distributing herbal products in Indonesia. This analysis not only places regulations as a normative framework, but

also examines the suitability between legal provisions and empirical conditions that develop in the traditional medicine industry. This approach is expected to provide a more comprehensive picture of the effectiveness of the licensing system and its implications for consumer protection. This study discusses the legal status of Traditional Medicine Industry Licensing in the Risk-Based Business Licensing system according to statutory regulations, as well as legal provisions regarding violations of the traditional medicine industry according to Law Number 17 of 2023 concerning Health (hereinafter referred to as Law 17/2023) and regulations of the Food and Drug Supervisory Agency (hereinafter referred to as BPOM) (10).

METHOD/IDEA

Legal research is a step or process that aims to produce legal regulations, legal principles, and legal doctrines to answer existing legal problems (11), and so that the writing is arranged systematically and the data obtained is reliable and accurate, the method used is very important in determining the course of the research. This research uses a statutory approach (*statute approach*) to analyze the provisions in Law 17/2023, Government Regulation Number 28 of 2025 (hereinafter referred to as PP 28/2025), and BPOM Regulation Number 29 of 2023, with a normative juridical research type that aims to find legal principles, legal rules, and legal doctrines to answer legal issues that are the focus of the research (12). This research is descriptive-analytical using secondary data that includes primary and secondary legal materials (13), where primary legal materials include Law Number 11 of 2020 which has been amended by Law Number 6 of 2023 concerning Job Creation (hereinafter referred to as Law 6/2023), Law Number 17 of 2023 concerning Health, Government Regulation Number 28 of 2025, and BPOM Regulation Number 29 of 2023, while secondary legal materials consist of legal literature, scientific journals, and previous research results relevant to the licensing of the traditional medicine industry. Data collection was conducted through literature study by tracing, understanding, and reviewing laws and regulations, books, and scientific journals, then analyzed using deductive logic with a major premise in the form of legal norms and a minor premise in the form of legal facts to draw conclusions regarding the suitability of traditional medicine industry licensing regulations with their implementation in Indonesia and provide legal recommendations for improving future industrial practices.

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RESULTS AND DISCUSSION

A. Legality of KBLI 21022 Industry

1. Position of KBLI in the National Business Licensing System

KBLI 21022 is a normative code that regulates the traditional medicinal product industry for humans and in the risk-based business licensing system as stipulated in Law 6/2023 concerning Job Creation, this KBLI is the main foundation of the industry's legality because it determines the level of risk, the type of permit, and the sectoral oversight mechanism by the BPOM. Business licensing is understood as a state administrative decision that provides legal legitimacy for economic activities that are in principle prohibited without state administrative approval, so the legal standing of the traditional medicine industry depends on the correct KBLI classification. Philipus M. Hadjon explains that a permit is a form of *beschikking* or state administrative decision that is concrete, individual, and final (14). Thus, the position of KBLI in the national licensing system is constitutive because it is the basis for identifying business activities, determining risk levels, and the entry point for legality through the system *Online Single Submission* (hereinafter referred to as OSS).

In the risk-based licensing system based on PP 28/2025, the determination of low, medium-low, medium-high, and high risk categories is carried out based on the KBLI code listed by the business actor. Ridwan HR emphasized that administrative authority must be exercised based on the principle of legality (15). Therefore, KBLI ensures that every business activity is normatively mapped and can be linked to the authority of a particular ministry or technical agency. If the KBLI does not correspond to actual activities, the issued permit may contain substantive defects or authority defects and has the potential to be null and void or revoked. According to Utrecht, administrative decisions based on incorrect facts have the potential to lose their validity (16).

2. KBLI 21022 as the Legal Basis for the Traditional Medicine Industry

KBLI 21022 specifically regulates the Traditional Medicine Products Industry for Humans, which includes the production of herbal medicines, Standardized Herbal Medicines (hereinafter referred to as OHT), and phytopharmaceuticals (17). This classification aligns with the BPOM's classification of traditional medicines based on the level of scientific evidence, making KBLI 21022 not merely an administrative code, but a legal instrument that determines the scope of industrial production authority. The concept of legal standing in administrative law

refers to the legitimate legal standing for legal subjects to carry out actions based on the authority granted by statutory regulations. Madril and Hasinanda explain that legal standing arises from formal and material aspects (18).

Formally, business actors are required to have a Business Identification Number (hereinafter referred to as NIB), a Standard Certificate according to the risk level, and a production permit from the BPOM (National Agency of Drug and Food Control) as stipulated in Law 6/2023 and Government Regulation 28/2025. The traditional medicine industry is categorized as a medium-high to high-risk business and therefore requires strict verification before operating. Without the inclusion of KBLI 21022 in the NIB, a business entity lacks the administrative legitimacy to produce traditional medicines and its operational legality is flawed from the outset (*defect in authority*). Production without a basis of authority can be categorized as an act without authority (*incompetence*) or abuse of power.

In addition to formal aspects, the traditional medicine industry is required to comply with material aspects in the form of Good Manufacturing Practices for Traditional Medicines (hereinafter referred to as CPOTB), which include the arrangement of buildings, facilities, equipment, hygiene, quality control, documentation, and personnel competence. This obligation is a manifestation of the precautionary principle in health law and the state's responsibility to protect the right to health as guaranteed in Law Number 36 of 2009 (hereinafter referred to as Law 36/2009). In Indonesian society, which is predominantly Muslim, the aspect of product safety is also related to the guarantee of the halalness of the ingredients used, so that traditional medicinal products in principle need to pay attention to halal standards as regulated in the national halal product assurance system (19). Production without KBLI 21022 and without compliance with CPOTB can be subject to administrative sanctions in the form of written warnings, temporary suspension, freezing of permits, up to revocation of permits, and under certain conditions can have criminal implications (20).Thus, the legal status of a traditional medicine industry is determined not only by the possession of the required administrative permits but also by compliance with stringent substantive standards.

3. Industrial Licensing in PP 28 of 2025

Government Regulation 28 of 2025 emphasizes that every business activity is classified based on its risk level. The traditional medicine industry is categorized as a high-risk business, considering that its products directly impact public health and have the potential to cause serious

impacts if they do not meet safety, efficacy, and quality standards. Therefore, business actors are required to obtain a full operational permit before production and distribution begin. This approach reflects the principle of *preventive supervision*, which refers to regulatory oversight conducted prior to the commencement of business activities. The required licensing documents include the Business Identification Number (NIB), Verified Standard Certificate, Good Manufacturing Practice for Traditional Medicines (CPOTB) certification, production permits, and the Marketing Authorization Number (NIE).

Article 45 of PP 28 of 2025 stipulates that business actors who do not meet standards may be subject to gradual administrative sanctions in the form of written warnings, temporary suspension, permit suspension, and permit revocation (21). From an administrative law perspective, administrative sanctions have both a preventive and repressive character. Preventive because they aim to stop violations as early as possible, and repressive because they impose legal consequences for business actors' non-compliance. Although the normative framework is appropriate, illegal products are still found being marketed through online platforms without production permits and distribution permits, thus giving rise to implications of unfair business competition, increased public health risks, and reduced effectiveness of the risk-based licensing system (5).

4. NIE Obligations as Industrial Output

The Marketing Authorization Number (NIE) represents the final output of the licensing process and is directly related to the legality of products circulating in the market. The NIE serves as evidence of compliance with regulatory requirements as well as an instrument of consumer protection. From an administrative law perspective, it constitutes a concrete, individual, and final administrative decision (22). The issuance process of the Marketing Authorization Number (NIE) involves the evaluation of ingredient composition, laboratory testing, safety assessments, verification of efficacy claims, and labeling inspections. These stages reflect the principle of preventive control. Through this process, the state exercises its regulatory function to ensure that only products meeting established standards are allowed for public consumption. This system is consistent with the precautionary principle in health law.

The use of fictitious NIEs or falsified distribution permits constitutes a serious violation that can be subject to administrative and criminal sanctions. Administratively, business actors can be subject to sanctions in the form of revocation of production permits, freezing of business

activities, and withdrawal of products from circulation. On the other hand, perpetrators can be held criminally responsible if their actions cause harm or endanger public health. The existence of NIEs is a form of preventive legal protection for consumers and a manifestation of the state's responsibility in ensuring public safety (23). Thus, the legal position of traditional medicine industry licensing (KBLI 21022) in the risk-based business licensing system is central, constitutive, and determines the validity of the industry's legal standing according to statutory regulations.

B. Violations of the Traditional Medicine Industry

1. Use of Fictitious NIE as Legal Fraud

The normative regulations regarding violations in the traditional medicine industry in Law 17/2023 concerning Health place licensing and safety standards as the primary foundation for public protection. The production and distribution of traditional medicines are inextricably linked to the obligation to possess a Marketing Authorization (NIE), issued by the government through strict administrative mechanisms. The NIE is a concrete and individual state administrative decision, granting business actors the legal right to distribute their products legally. Within the framework of Indonesian national health law, any action that ignores the requirement for a marketing authorization or manipulates the legality of a product constitutes a violation of the applicable legal system. This is emphasized in Law Number 17 of 2023 concerning Health, which requires all pharmaceutical preparations, including traditional medicines, to possess a marketing authorization before being marketed. This regulation emphasizes not only administrative aspects but also requires compliance with safety, efficacy, and quality standards as a form of public protection, under supervision by the Food and Drug Monitoring Agency (BPOM). Violations of these provisions can result in administrative and criminal sanctions in accordance with applicable laws and regulations.

The use of fictitious NIEs is a serious violation in the traditional medicine industry because it manipulates state legal instruments for economic gain. In various monitoring findings by the BPOM, illegal herbal products often include fictitious NIEs or use numbers belonging to other products to create the impression that they have obtained official government approval (24). This action not only undermines the drug and food control system but also threatens public safety because the products in circulation do not go through the proper safety, quality, and

efficacy evaluation process. Normatively, falsifying NIEs can be qualified as falsifying official state documents because distribution permits are state administrative decisions that give rise to legal rights (25). The use of fictitious NIEs also violates Article 435 of Law No. 17 of 2023 concerning Health, which provides for sanctions against the distribution of pharmaceutical products without valid marketing authorization. From both civil law and business ethics perspectives, such conduct contravenes the principle of good faith in trade, as it involves elements of misrepresentation.

The pattern of NIE misuse indicates deliberate business activity exploiting low consumer legal literacy and limited public access to verification. This misuse can include the inclusion of numbers never issued, the use of numbers belonging to other products, falsifying packaging, or creating number formats that resemble official systems. Legally, this action fulfills the elements of document forgery as stipulated in Article 263 of the Criminal Code because the document creates rights and is used to obtain economic gain. In health law, this violation also constitutes the act of distributing pharmaceutical preparations without a permit as stipulated in Article 435.

2. Use of BKO in Traditional Medicinal Products

In addition to the use of fictitious NIEs, another prominent normative violation is the mixing of BKO in traditional medicinal products. The BPOM, in various monitoring results, found that a number of illegal herbal products contained BKO that was deliberately mixed to produce instant effects (4). This practice contradicts the basic concept of traditional medicine, which should be made from natural ingredients and free from synthetic chemicals. This is emphasized in Law Number 17 of 2023 concerning Health, which requires every pharmaceutical preparation to meet safety, efficacy, and quality standards. In addition, Article 7 of the Food and Drug Supervisory Agency Regulation Number 32 of 2019 concerning Safety and Quality Requirements for Traditional Medicines expressly prohibits traditional medicines from containing Chemical Medicinal Ingredients (BKO). However, in practice, substances such as sildenafil, dexamethasone, paracetamol, or sibutramine are still found that are not listed on the label, thus violating legal provisions and potentially endangering consumers. However, in practice, substances such as sildenafil, dexamethasone, paracetamol, or sibutramine are often added without being listed on the composition label, thus not only violating statutory provisions but also potentially endangering consumer health. The addition of BKO not only violates regulatory provisions but also poses serious health risks due to the lack of dosage monitoring and

potential drug interactions (26). Ethically, this action misleads consumers because the information on the label does not reflect the actual content. From a health law perspective, this practice violates the principles of safety, efficacy, and caution that are the basis for public protection.

Normatively, the production or distribution of traditional medicines containing BKO without a distribution permit can be prosecuted under Article 435 of Law 17/2023 concerning Health. This provision stipulates criminal penalties for anyone who produces or distributes pharmaceutical preparations that do not meet safety, efficacy, and quality standards or does not have a distribution permit. Criminal penalties can reach a maximum of twelve years in prison and a large fine of up to billions of rupiah (27). The character of this article is both a formal and material offense because the criminal element is fulfilled when the product is distributed without a permit, and becomes more severe if it causes real harm. This regulation demonstrates a strict preventive approach in protecting public health.

3. BPOM Administrative Actions Against Illegal Industries

In administrative law enforcement practices, the BPOM has strategic authority to supervise and take action against illegal industries based on Article 182 of Law 17/2023 concerning Health. This authority includes *pre-market* supervision through the evaluation of distribution permits and inspection of production facilities, as well as *post-market* supervision through sampling, laboratory testing, and cyber patrols. Administrative measures are aimed at restoring public order (*restoration of order*) and promptly preventing potential harm. In practice, BPOM can take various actions against illegal industries, including (28):

1. Product Withdrawal from Circulation (*Recall*), namely an order to withdraw products that do not meet standards in order to stop potential consumer losses;
2. Confiscation of evidence as part of the process of taking action and proving violations;
3. Destruction of hazardous products to prevent recirculation;
4. Recommendations for revoking business permits to the authorized agency if violations are committed by licensed business actors.

Administrative sanctions are swift, flexible, and corrective because they can be applied without waiting for a court decision. Their primary focus is to stop the danger and restore market conditions to a state consistent with the law. In administrative law theory, this approach differs from criminal law, which emphasizes retaliation. However, if the violation is serious, repeated,

or involves a clear intentional element, law enforcement can shift to the criminal realm as an *ultimum remedium*. This transition demonstrates the complementary relationship between administrative and criminal sanctions in the health law system. This phased approach is intended to maintain a balance between effective public protection and proportional law enforcement.

Although BPOM's administrative authority is quite broad, the effectiveness of supervision faces a number of challenges, including (29):

a. The rise of distribution through online platforms;
b. Home-scale production that is difficult to detect;
c. Rapid relocation of production locations;
d. Limited supervisory resources.

These challenges demonstrate that violations in the traditional medicine industry are not only normative but also structural and sociological. Without the integration of online verification systems and public participation in reporting, risk-based oversight will not be optimal. Therefore, strengthening cross-sector coordination and utilizing information technology are crucial for regulatory implementation.

4. Criminal Liability (Article 435 of Law 17 of 2023)

Article 435 of Law 17/2023 provides the legal basis for criminal penalties for anyone who produces or distributes pharmaceutical preparations and/or medical devices that do not meet safety, efficacy, and quality standards, and/or do not possess a distribution permit. This provision constitutes a core norm (*core penal provision*) in modern health law, as it directly criminalizes the distribution of illegal health products that have the potential to harm the public. Article 435 of Law 17/2023 stipulates a criminal penalty of up to 12 (twelve) years' imprisonment or a maximum fine IDR 5.000,000,000.00 (five billion rupiah). This relatively serious criminal threat shows that violations in the health sector are seen as serious crimes.The rationale is because the impacts are not only individual, but can also be widespread and systemic.

Article 435's primary focus is protecting the right to public health. By criminalizing the distribution of products without permits or products that do not meet standards, the law emphasizes that administrative legality is not merely a formality, but a substantive prerequisite for public protection. However, the effectiveness of this article depends on consistent law enforcement, coordination between the Food and Drug Authority (BPOM) and law enforcement officials, the ability to prove criminal elements, and the transparency of the judicial process.

Therefore, Article 435 serves as a key pillar in the public health protection system through criminal law enforcement mechanisms.

CLOSING

The legal status of KBLI 21022 in the risk-based business licensing system has a central and constitutive role because it is the basis for identifying business activities, determining risk levels, and determining licensing obligations for the traditional medicine industry, so that it does not merely function as an administrative code but also as an instrument that determines the legal standing of business actors in producing herbal medicines, OHT, and phytopharmaceuticals legally. The legality of industrial operations is determined by the fulfillment of formal aspects such as NIB, verified Standard Certificate, production permit, and NIE, as well as material aspects in the form of fulfillment of CPOTB standards as a form of the precautionary principle in health law, where the inconsistency between KBLI and real activities can have implications for defects in authority or substance that have the potential to revoke business permits. In addition, normative regulations emphasize that violations such as production without NIE, use of fictitious NIE, and mixing of BKO constitute serious violations of the national health law system as stipulated in Law Number 17 of 2023 concerning Health, specifically Article 435 which regulates severe criminal sanctions, because these actions not only damage the legitimacy of the licensing system but also endanger public health and violate consumer rights. In this case, the Food and Drug Monitoring Agency has the authority to carry out administrative actions such as withdrawal, confiscation, destruction, and recommendations for revocation of permits, while criminal law enforcement is applied as an *ultimum remedium* if the violation is committed seriously, repeatedly, or intentionally.

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