Regulatory compliance index of traditional medicine and health supplement companies in Indonesia

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Abstract. The traditional medicine and health supplement sectors are growing in Indonesia, driven by public interest in natural and preventive health solutions. Regulatory compliance is essential to ensure the safety, quality, and efficacy of these products. This study aims to assess the compliance level of traditional medicine and health supplement companies or business actors with applicable regulations and standards in Indonesia. The measurement was conducted by The Indonesian Food and Drug Authority (The Indonesian FDA), which supervises the entire life cycle of these products. The method involved a quantitative analysis of data from the inspection of production facilities, distribution, advertising, and labelling, conducted by Indonesian FDA Regional Office in 34 provinces. The data were classified into compliant and non-compliant categories, then analyzed by measuring the proportion of comply facilities out of the total facilities, and weighted using the Analytical Hierarchy Process approach. Results showed that health supplement companies have higher and more stable compliance than traditional medicines companies. The compliance index for traditional medicines during 2020-2024 ranged from 66.83-85.26, while health supplements ranged from 90.73-97.80. Fluctuations in index values in the traditional medicine sector indicate the need to strengthen guidance and stricter regulatory supervision. This study is an important instrument to evaluate the effectiveness of The Indonesian FDA control and support the improvement of national industry competitiveness.

1. Introduction

Technological advances have brought about rapid and significant changes in the pharmaceutical industry, including herbal medicines and health supplements [1]. Through the application of modern technology, this industry is able to produce a wide range of products on a large scale with a wide distribution range to all corners of Indonesia. However,

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the ease of access to these products also brings great challenges in terms of supervision to ensure the safety, efficacy, and quality of products in circulation [2].

Traditional medicine is an ingredient or combination of ingredients in the form of plant materials, animal materials, mineral ingredients, galenic preparations, or a mixture of these ingredients that have been used for generations for treatment, and can be applied in accordance with applicable norms in the community [3]. Meanwhile, health supplements are products intended to complement nutritional needs, maintain, increase and/or improve health functions, have nutritional value and/or physiological effects, contain one or more ingredients in the form of vitamins, minerals, amino acids and/or other non-plant ingredients that can be combined with plants [4]. Both are an important part of the traditional and complementary health system whose existence needs to be supervised by regulation to ensure its safety and effectiveness for the community.

The Indonesian FDA is present as the main authority that regulates and supervises the entire life cycle of these two products, from raw material procurement to distribution and public consumption [5]. The Indonesian FDA consistently encourages companies to comply with applicable regulations and standards, such as the Good Manufacturing Practice (GMP) for traditional medicines and health supplements, Good Distribution Practice (GDP), The Indonesian FDA Regulation No. 34 of 2022 regulating the supervision of advertising of traditional medicines, quasi medicines, and health supplements, The Indonesian FDA Regulation No. 10 of 2024 concerning labelling and other applicable regulations. These efforts are an important part of protecting public health and ensuring the quality of products on the market [3].

One of The Indonesian FDA's commitments is to increase companies compliance with established regulations. Compliance indicators are measured through the regulatory compliance index. The measurement is based on secondary data from inspection of production, distribution facilities, advertising, and labelling collected by Indonesian Food and Drug Authority Regional Office throughout Indonesia.

Compliance is an attitude and action to know and follow applicable laws, regulations, principles, standards, and procedures [6]. This compliance is very important for companies in carrying out their business operations [7]. Business actors as intended include individuals or business entities, whether incorporated or not, which are established and operate in the jurisdiction of Indonesia, including owners of production and distribution facilities, large and small traders, importers, and applicants for drug and food product notifications [8]. In the context of The Indonesian FDA control, compliance of companies or business actors means their adherence to regulations to ensure that the products they produce and distribute meet safety, efficacy, and quality requirements [3].

The control of traditional medicines and health supplements is an important aspect of consumer protection, encompassing multidimensional efforts and requiring cross-sectoral coordination [9]. A key strategy in this context is the implementation of Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) specific to traditional medicines and health supplements. These, along with other relevant regulatory frameworks, aim to ensure that every product manufactured and distributed adheres to established quality and safety standards [3].

Efforts to increase literacy and capacity of companies or business actors are carried out through socialization and technical guidance activities in various regions of Indonesia. Through the analysis of compliance trends and the factors that influence them, this study is expected to make a concrete contribution to the evaluation of regulatory policies and provide data-driven recommendations to strengthen the control system in the field of traditional medicine and health supplements. This effort forms an important part of the evaluation of control and guidance programs that have been carried out by the government and aims to assess the extent to which companies in the traditional medicine and health supplement sector

comply with applicable regulations in Indonesia. In line with this, the study specifically aims to assess the compliance level of traditional medicine and health supplement companies or business actors with applicable regulations and standards. The results are expected to serve as a key instrument to evaluate the effectiveness of drug and food control policies that have been implemented by the government. High compliance with regulations will not only protect consumers, but also increase the competitiveness of the Indonesian pharmaceutical industry at the national and global levels.

2. Method

The methodology used is a desk study approach, which is a quantitative analysis using data from the inspection of production facilities, distribution, advertising, and marking of traditional medicines and health supplements. The inspection was conducted by Indonesian FDA Regional Office using a risk-based method. The data obtained were categorized into compliant and non-compliant conditions. Verification of data assessment is done by converting the compliance status of facilities into categories: A (good), B (satisfactory), and C (poor). Subsequently, the percentage of compliance for each category was calculated for statistical analysis using the Top One Box/Top Two Boxes method by measuring the proportion of facilities graded A (Top One Box) or A and B (Top Two Boxes) out of the total facilities as also used in other food and pharmaceutical sector compliance study [10]. Weightings were then applied to production facilities, distribution, advertising and labeling using the Analytical Hierarchy Process (AHP) method, resulting in a compliance index for each product category. The compliance index is categorized into four levels: very good (>90–100), good (>66.67–90), fair (>33.33–66.67), and poor (0–33.33). The standards that must be met by production facilities are Good Manufacturing Practice (GMP) [11] and Good Manufacturing Practice (GMP) for Traditional Medicines [3], while for distribution facilities are Good Distribution Practice (GDP) [12], then for advertising is The Indonesian FDA Regulation No. 34 of 2022 regulating the Supervision of Advertising of Traditional Medicines, Quasi Medicines, and Health Supplements [13], and for labeling herbal medicines and health supplements is The Indonesian FDA Regulation No. 10 of 2024 [14].

3. Results and Discussion

The number of inspections of production and distribution facilities, advertising and labelling of traditional medicine products carried out by The Indonesian FDA in 2020-2024 ranged from 2,204 to 3,980 (Figure 1), indicating an increasing trend in the scope of regulatory supervision from year to year. Meanwhile, the number of inspections manufacturing and distribution facilities, advertising and labelling of health supplement products conducted by The Indonesian FDA during the same period ranged from 552 to 1,470 (Figure 2). This range reflects the increasing attention and regulatory oversight of traditional medicine and health supplement products in recent years [15].

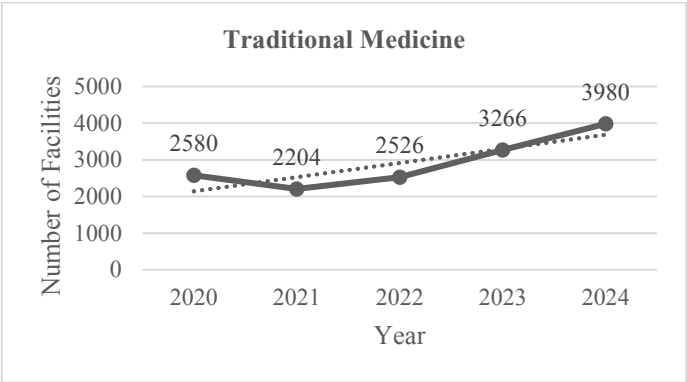

Fig 1. Number of Traditional Medicine Facilities Inspected by The Indonesian FDA in 2020 - 2024.

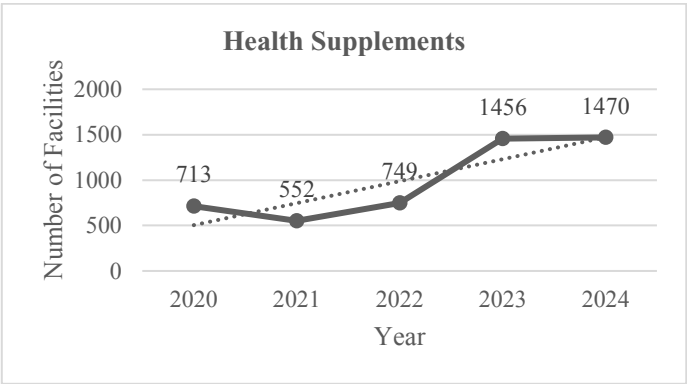

Fig 2. Number of Health Supplement Facilities Inspected by The Indonesian FDA in 2020 - 2024.

The compliance index graph from 2020 to 2024 (Figure 3) shows that health supplements consistently show a higher level of compliance than traditional medicines. Although the compliance index for traditional medicines increased gradually from 66.83 in 2020 to 89.05 in 2022, it decreased slightly to 87.74 in 2023 and continued to decrease to 85.26 in 2024 [15]. This shows that there are challenges in maintaining compliance with regulations. The strict process of distribution licensing and supervision can reduce the risk of circulating unsafe or unqualified products. In addition, regulations also require manufacturers and sellers to include clear and accurate information on product labels, which can help consumers make informed and wise decisions.

In contrast, the health supplement index remained consistently high, although it declined slightly in 2021, and peaked at 97.80 in 2023 before declining slightly to 94.43 in 2024 [15]. This means that companies in this sector have a better understanding of regulations, and a higher willingness to adapt, which is then reflected in the consistently high index score. As a follow-up, increasing the intensity of technical guidance, drafting more detailed guidelines, and providing concrete examples of non-misleading advertising criteria are recommended to further strengthen companies or business compliance. This compliance is also closely related to the quality management system, personnel, buildings and facilities, equipment, sanitation and hygiene, production, quality control, self-inspection, complaints and recalls, documentation, contracts, qualifications, and validation [3, 11], which are important components in the assessment of production aspects in this study.

Overall, the data shows that the health supplement industry exhibits stronger and more stable compliance with standards/regulations compared to traditional medicines. This difference reflects the effectiveness of regulations and supervision implemented by The

Indonesian FDA. The Indonesian FDA has issued various regulations to improve production and distribution standards. In addition, The Indonesian FDA emphasizes the importance of GMP and GDP compliance to ensure product quality and safety. The health supplement industry seems to be more adaptive to these regulatory changes, which is reflected in the consistently high compliance index. However, the fluctuating trend of the compliance index in traditional medicine suggests the need for stronger regulatory implementation, more intensive and continuous coaching and guidance, and stricter monitoring. This is important to ensure that all products, both health supplements and traditional medicines, meet the quality and safety standards set by the government [15].

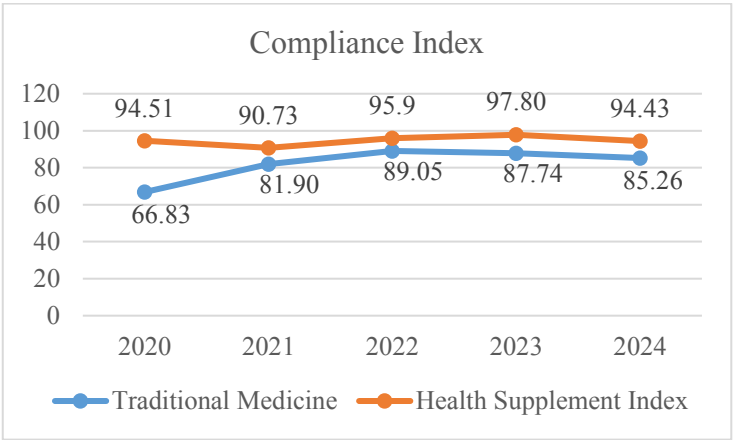

Fig 3. Compliance Index of Traditional Medicine and Health Supplement Business Actors 2020 - 2024.

Supervision of pharmaceutical preparations, especially traditional medicines and health supplements is an important part of consumer protection efforts and enforcement of product quality standards in Indonesia. The process of registration and supervision of traditional medicine brands by The Indonesian FDA has a crucial role in ensuring that products meet safety, efficacy, and quality requirements [5]. In a broader context, The Indonesian FDA has developed a data-based evaluative approach to assess the effectiveness of supervision of companies, one of which is through the measurement of the companies or business actors compliance index which is designed to measure the level of compliance of companies including traditional medicines and health supplements with applicable regulations. The indicator components in this measurement include the results of inspection of production and distribution facilities, fulfillment of standards such as GMP and GDP, as well as the results of supervision of advertising and product labelling.

4. Conclusion

From 2020 to 2024, the compliance index for traditional medicine companies ranged from 66.83 to 85.26. In 2024, their compliance level was classified in the good category. In comparison, health supplement companies showed higher and more consistent compliance levels, with index values ranging from 90.73 to 97.80 during the same period. In 2024, their compliance was categorized as very good. This indicates that health supplement companies generally demonstrate strong and stable compliance with standards and regulations. These findings highlight the need for stronger regulatory implementation for traditional medicine companies, including more intensive and sustained guidance, mentoring, and monitoring to improve compliance levels across the sector.

Reference

1. N. S. Arden, A. C. Fisher, K. Tyner, L. X. Yu, S. L. Lee, and M. Kopcha, Industry 4.0 for pharmaceutical manufacturing: Preparing for the smart factories of the future, Int. J. Pharm. **602**, 120554 (2021). https://doi.org/10.1016/j.ijpharm.2021.120554.
2. O. O. Ogbuagu, A. O. Mbata, O. D. Balogun, O. Oladapo, O. O. Ojo, and M. Muonde, Quality assurance in pharmaceutical manufacturing: Bridging the gap between regulations, supply chain, and innovations, Int. J. Multidiscip. Res. Growth Eval. **4**, 823 (2023). https://doi.org/10.54660/.IJMRGE.2023.4.1-823-831.
3. BPOM, Peraturan Badan Pengawas Obat dan Makanan Nomor 25 Tahun 2021 Tentang Cara Pembuatan Obat Tradisional yang Baik (The Indonesian FDA Regulation Number 25 of 2021 concerning Good Traditional Medicine Manufacturing Methods) (2021) [In Indonesia].
4. BPOM, Peraturan Badan Pengawas Obat dan Makanan Nomor 24 Tahun 2023 tentang Persyaratan Keamanan dan Mutu Suplemen Kesehatan (The Indonesian FDA Regulation Number 24 of 2023 on Safety and Quality Requirements for Health Supplements) (2023) [In Indonesia].
5. T. S. Jan, T. Handayani, and M. Sueb, Supervision and registration of traditional medicine brands in Indonesia, Nagari Law Rev. **5**, 87 (2021). http://dx.doi.org/10.25077/nalrev.v.5.i.1.p.87-92.2021.
6. I. A. Adeniran, A. O. Abhulimen, A. N. Obiki-Osafiele, O. S. Osundare, E. E. Agu, and C. P. Efunniyi, Strategic risk management in financial institutions: Ensuring robust regulatory compliance, Finance Account. Res. J. **6**, 1582 (2024). http://dx.doi.org/10.51594/farj.v6i8.1508.
7. R. Mahanti, Data governance and compliance, in Data Governance and Compliance: Evolving to Our Current High Stakes Environment (Springer, Singapore, 2021), pp. 109-153. http://dx.doi.org/10.1007/978-981-33-6877-4.
8. BPOM, Peraturan Badan Pengawas Obat dan Makanan Nomor 25 Tahun 2023 Tentang Kriteria dan Tata Laksana Registrasi Obat Bahan Alam (The Indonesia FDA Regulation Number 25 of 2023 concerning Criteria and Procedures for Registration of Natural Medicines) (2023) [In Indonesia].
9. E. Etiaba, P. Agwu, L. Conteh, and O. Onwujekwe, Multisectoral contributions to health security and formal policy availability at the community level in Nigeria, Front. Public Health **13**, 1505383 (2025). https://doi.org/10.3389/fpubh.2025.1505383.
10. M. Jaberidoost, S. Nikfar, A. Abdollahiasl, and R. Dinarvand, Pharmaceutical supply chain risk assessment in Iran using analytic hierarchy process and simple additive weighting methods, J. Pharm. Policy Pract. **8**, 9 (2015). https://doi.org/10.1186/s40545-015-0029-3.
11. BPOM, Peraturan Badan Pengawas Obat dan Makanan Nomor 7 Tahun 2024 Tentang Standar Cara Pembuatan Obat yang Baik (2024) [The Indonesian FDA Regulation Number 7 of 2024 concerning Standards for Good Manufacturing Methods (2024) [In Indonesia].
12. BPOM, Peraturan Badan Pengawas Obat dan Makanan Nomor 6 Tahun 2020 Tentang Pedoman Teknis Cara Distribusi Obat yang Baik (2020) (The Indonesian FDA Regulation Number 6 of 2020 on Technical Guidelines for Good Drug Distribution Methods) (2020) [In Indonesia].

13. BPOM, Peraturan Badan Pengawas Obat dan Makanan Nomor 34 Tahun 2022 Tentang Pengawasan Periklanan Obat Tradisional, Obat Kuasi, dan Suplemen Kesehatan (The Indonesian FDA Regulation No. 34 of 2022 on the Supervision of Advertising of Traditional Medicines, Quasi-Medicines, and Health Supplements) (2022) [In Indonesia].
14. BPOM, Peraturan Badan Pengawas Obat dan Makanan Nomor 10 Tahun 2024 Tentang Penandaan Obat Bahan Alam, Obat Kuasi, dan Suplemen Kesehatan (The Indonesian FDA Regulation No. 10 of 2024 on the Marking of Natural Medicines, Quasi Medicines, and Health Supplements) (2024) [In Indonesia].
15. BPOM. Kegiatan Pengukuran Indeks Kepatuhan (Compliance Index) Pelaku Usaha di Bidang Obat dan Makanan Tahun 2024 [Compliance Index Measurement Activity for Business Actors in the Field of Medicines and Food, 2024] (2025) [In Indonesia].