

Profile of Herbal Medicine Registration Documents Compliance in 2021–2023 for Stunting Prevention

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ABSTRACT / ABSTRAK

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Stunting is one of the indicators of social and economic problems in a country. As part of efforts to prevent stunting, one of the strategies that can be implemented is the use of herbal medicines. This study examines the registration process for herbal medicines aimed at preventing stunting, submitted to the Indonesian Food and Drug Authority (Badan POM) between 2021 and 2023. A total of 900 products have been registered with an increasing annual trend, indicating high interest from businesses in producing and registering these products. Although awareness of the importance of product registration to ensure safety and quality has increased, there are still significant issues related to the incompleteness of the necessary documents. This research showed that, on average, 77% of product submissions were still incomplete, particularly from the UKOT group, which accounted for 90%. This analysis found that aspects of quality and labeling often failed to meet the standards set by Badan POM Regulation No. 25 of 2023. The study suggests that simplifying the registration procedures and more targeted interventions, such as the provision of educational materials and more intensive training, can help address these issues. Additionally, the research recommends further surveys to specifically identify the obstacles faced by businesses, which will assist in the design of more effective policies to support the improvement of quality and speed in the product registration process in the future.

Stunting menjadi salah satu indikator dari permasalahan sosial dan ekonomi dalam suatu negara. Dalam rangka melakukan pencegahan stunting, salah satu upaya yang dapat dilakukan adalah pemberian obat tradisional. Pada penelitian ini dilakukan kajian proses registrasi produk obat tradisional untuk pencegahan stunting yang diajukan ke Badan Pengawas Obat dan Makanan (Badan POM) Indonesia selama periode 2021–2023. Sebanyak 900 produk telah didaftarkan dengan tren peningkatan tahunan, menunjukkan tingginya minat pelaku usaha dalam memproduksi dan mendaftarkan produk tersebut. Meskipun kesadaran akan pentingnya registrasi produk untuk memastikan keamanan dan mutu telah meningkat, masih terdapat masalah signifikan terkait dengan ketidaklengkapan dokumen yang diperlukan. Penelitian ini menunjukkan bahwa rata-rata 77% dari pengajuan produk masih belum lengkap dan kelompok usaha yang paling banyak mengajukan adalah Usaha Kecil Obat Tradisional (UKOT). Dari kelompok UKOT, pengajuan yang belum lengkap mencapai 90%. Analisis ini menemukan bahwa aspek mutu dan penandaan sering kali tidak memenuhi Peraturan Kepala BPOM Nomor 25 tahun 2023 tentang Kriteria dan Tata Laksana Registrasi Obat Bahan Alam. Penelitian ini menyarankan bahwa penyederhanaan prosedur registrasi dan intervensi yang lebih ditargetkan, seperti penyediaan materi sosialisasi dan pelatihan lebih intensif, dapat membantu mengatasi masalah ini. Selain itu, penelitian merekomendasikan survei lebih lanjut untuk mengidentifikasi secara spesifik hambatan yang dihadapi pelaku usaha, membantu dalam merancang kebijakan yang lebih efektif untuk mendukung peningkatan kualitas dan kecepatan proses registrasi produk di masa depan.

Keywords: stunting, herbal medicine, traditional medicine, product registration
Kata Kunci: stunting, obat herbal, obat tradisional, registrasi produk

1. Introduction

Stunting is a chronic nutritional disorder caused by prolonged nutrient deficiencies, which impairs children's physical growth, cognitive development, and future generational productivity (J et al., 2022). The prevalence of stunting serves as a critical indicator of a country's social and economic challenges (Nasrun & Rahmania, 2018; Musheiguza et al., 2023). The 2023 Indonesian Nutritional Status Survey, conducted by the Ministry of Health, reported that the prevalence of stunting in Indonesia remains high at 21.6%. (Kementerian Kesehatan RI, 2022). Stunting is also a national priority issue outlined in the 2020–2024 National Medium-Term Development Plan (RPJMN) (Pemerintah Republik Indonesia, 2020). This condition has long-term adverse impacts, including impaired physical growth and cognitive development (Mustakim et al., 2022). Ultimately, this reduces the quality of human resources and, consequently, affects national economic productivity in the long run. To accelerate the reduction of stunting, the utilization of safe and effective traditional medicines has emerged as a crucial solution.

One of the measures to prevent stunting is the use of herbal medicines with efficacy claims that support stunting prevention, such as improving nutritional value, preventing helminth infections (Kusuma et al., 2023), stimulating appetite (Kusuma et al., 2023), and promoting breast milk production (Subandrate et al., 2023). Previous studies, including that of Rahmah and Hassanah (2024), indicated that stunting prevention efforts may involve nutritional supplementation in both synthetic and herbal forms (Rahmah & Hasanah, 2024). Family Household medicinal plants, which are rich in nutrients, such as moringa leaves, have also been identified as alternatives for preventing stunting, particularly among pregnant women (Ifada et al., 2022).

The Directorate of Traditional Medicine, Health Supplements, and Cosmetics Registration (Dit. Reg OTSKK) of the Indonesian Food and Drug Authority (BPOM) conducts premarket registration evaluations for herbal medicinal products in accordance with BPOM's 2020 Strategic Plan. This evaluation covers the criteria of safety, quality, efficacy, and labeling, as stipulated in BPOM Regulation No. 25 of 2023. As a government institution, Dit. Reg OTSKK also supports the national stunting reduction program by expediting the marketing authorization of herbal medicinal products.

The registration process for traditional medicines involves assessing the documents submitted by applicants. These documents are evaluated according to a predetermined timeline. If corrections or additional data are required, applicants must provide the missing information within the specified deadline. Currently, stakeholders often face challenges in the registration process of herbal medicinal products, as evidenced by the frequent issuance of requests for additional registration data. These requests typically include administrative documents, safety, efficacy, quality, and labeling information that have not been fully completed during the registration process. Such challenges constitute obstacles to the issuance of marketing authorizations. This issue is reflected in the 2022 and 2023 Public Satisfaction Survey Reports of Dit. Reg OTSKK (Ditreg OTSKK, 2022, 2023), which

indicated that the service requirement scores were still lower compared to the other nine service components.

The issuance of marketing authorization for herbal medicines follows the provisions of BPOM Regulation No. 25 of 2023 on Criteria and Procedures for Herbal Medicine Registration, which require administrative, safety, efficacy, quality, and labeling documents (Badan POM, 2023). Compliance with these documentation requirements supports faster approval, ensuring the availability of herbal medicines in the market. The availability of herbal medicines for stunting prevention could support efforts to mitigate stunting. Ensuring that herbal medicines make a tangible contribution to reducing stunting prevalence is thus essential.

To date, no studies have analyzed the profile of herbal medicine registration document compliance for stunting prevention during 2021–2023. This research, therefore, aims to examine the completeness of registration documents based on the ASROT database, to determine the compliance profile of herbal medicine registration for stunting prevention at Dit. Reg OTSKK between 2021 and 2023. The profile can be utilized to identify challenges faced by businesses in preparing registration documents, thereby assisting them in compliance. The findings are also expected to provide recommendations for the Directorate to accelerate the issuance of marketing authorizations for herbal medicines aimed at preventing stunting.

2. Methodology

This study employed a descriptive design conducted at the Directorate of Traditional Medicine, Health Supplements, and Cosmetics Registration (Dit. Reg OTSKK) of the Indonesian Food and Drug Authority (BPOM). A total of 900 data entries were collected from the registration database (ASROT). The data included herbal medicinal products intended for stunting prevention, which were classified by business types (IOT, UKOT, UMOT, and importers) during the period from 2021 to 2023. Herbal medicinal products classified under stunting prevention included those with claims such as maintaining health by improving nutritional intake, stimulating appetite, preventing helminth infections, and promoting breast milk production.

The data obtained were analyzed using Microsoft Excel to determine median values. The analysis aimed to identify trends in the number of product submissions, the percentage of incomplete documentation, and document compliance profiles based on business type. Based on this analysis, the business group with the highest frequency of incomplete documents was examined further to assess aspects of registration document completeness, including administration, quality, efficacy/safety, and labeling/packaging.

3. Results and Discussion

3.1. Profile of Product Registration Submissions

Based on Figure 1, the number of herbal medicinal product submissions for stunting prevention registered with BPOM increased year by year from 2021 to 2023. The growing number of products indicates an increasing interest among business actors in producing herbal medicines that are beneficial for stunting prevention. Business actors have also become more aware of the importance of registering their products before market distribution to ensure the safety and quality of the products.

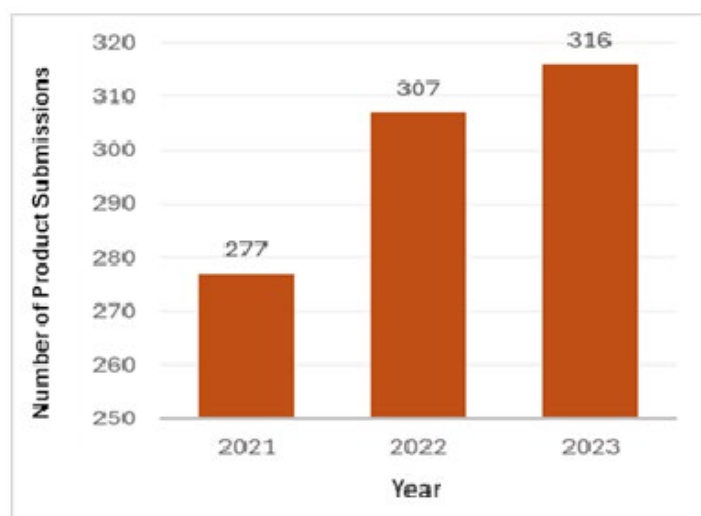


Figure 1. Number of Product Submissions

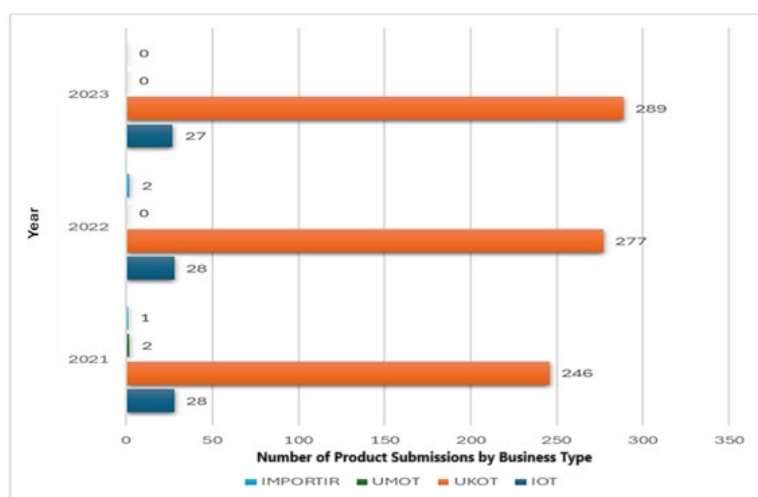


Figure 2. Number of Product Submissions by Business Type

As illustrated in **Figure 2**, most product submissions were registered by the Small-Scale Traditional Medicine Enterprises (UKOT). Both UKOT and Micro-Scale Traditional Medicine Enterprises (UMOT) fall under the Micro, Small, and Medium Enterprises (MSMEs) category; however, relatively few products were submitted by UMOT, with a submission ratio of 1:120 compared to UKOT. UMOT product submissions were extremely limited, totaling only 2 out of 900 products, and were restricted to raw herbal cuts. According to BPOM Regulation No. 25 of 2023, the dosage forms that UMOT can produce are limited to topical powders, plasters, ointments, external liquids, and raw herbal cuts. Meanwhile, herbal medicines for stunting prevention are commonly available in oral dosage forms, such as decoctions, powders, granules, pills, capsules, tablets, oral liquids, and other oral preparations, which can only be produced by UKOT or IOT. Importers rarely submitted herbal medicines for stunting prevention, as their target consumers mainly were middle- to upper-class groups who generally do not experience stunting. These findings align with a

study by Bustos et al. (2023), conducted among 3,005 children in the Philippines, which found a correlation between household welfare index and stunting prevalence, with children from low-welfare families more likely to suffer from stunting (Bustos et al., 2023).

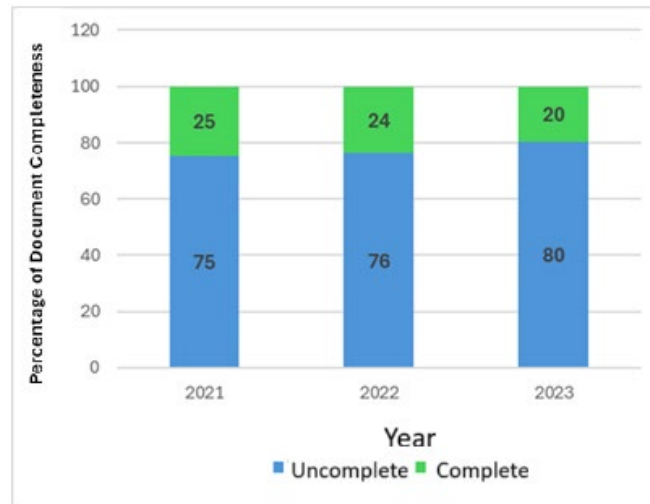


Figure 3. Percentage of Document Completeness

As shown in Figure 3, the proportion of incomplete documents at the time of submission was consistently higher than that of complete documents across all three years. The incompleteness rate, ranging between 75–80%, may be attributed to several factors, including limited understanding of registration regulations and procedures, as well as human resource constraints, which made it difficult for business actors to meet all requirements. This finding is consistent with Santiago and Estiningrum (2021), who demonstrated that the educational background of MSME operators significantly influences their level of understanding and perception (Santiago & Estiningrum, 2021). Businesses led by individuals with higher education levels tend to better comprehend registration requirements and procedures, thereby preparing documents more effectively.

3.2. Profile of Document Compliance

3.2.1 Compliance by Business Type

The mapping of incomplete registration submissions by business type revealed that the highest percentage of incomplete submissions came from UKOT, ranging from 88% to 91% (Figure 4). The rate of incompleteness remained consistently high and even increased by 3% in 2023 from 88% to 91%. This issue requires urgent attention, as the high percentage reflects insufficient understanding of the registration process among these businesses, necessitating more intensive and immediate interventions.

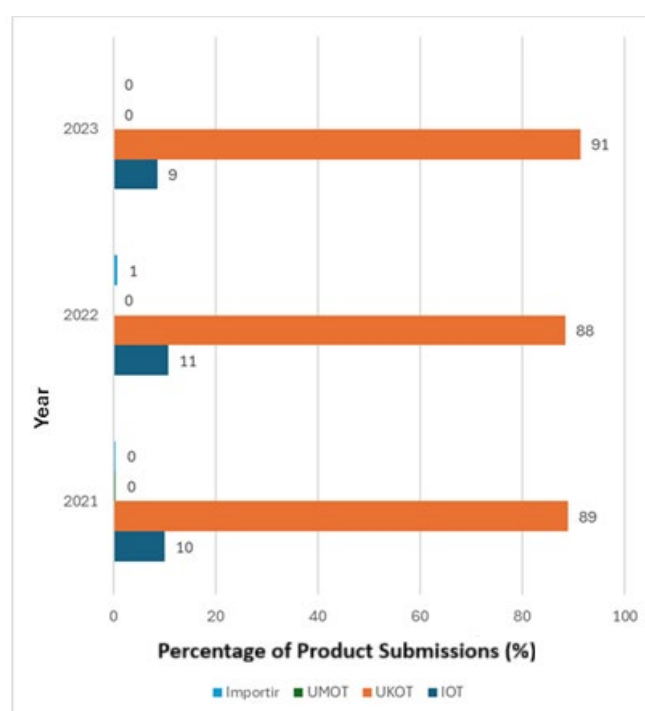


Figure 4. Percentage of Document Compliance by Business Type
(IOT: Traditional Medicine Industry, UKOT: Small-Scale Traditional Medicine Enterprise, UMOT: Micro-Scale Traditional Medicine Enterprise, Importers)

UKOT, as part of the MSME category, continues to face challenges in fulfilling registration document requirements, primarily due to the limited understanding of business actors regarding regulations and the requirements for registration. This analysis is supported by previous studies, which indicate that MSMEs generally have insufficient regulatory knowledge, largely due to limited access to information and outreach activities (Aisyah et al., 2023; Akim et al., 2019). Although these studies focused on food industry MSMEs, similar challenges are likely to occur among herbal medicinal product (HMP) business actors, considering that both sectors fall under the MSME category and share similar characteristics, such as limited human resources. This evidence suggests that lack of regulatory knowledge and restricted access to information can constitute a common barrier for MSMEs, including those in the herbal medicine sector. Human resources play a critical role in industry performance; therefore, enhancing competencies is essential to maintain competitive advantage over other enterprises (Tampubolon, 2016). Other studies also indicate that inadequate human resources and limited capital are significant constraints faced by MSMEs, which hinder their business development (Suryani, 2018).

Online product registration also requires business actors to possess adequate technological skills. Many MSMEs still face limitations in digital technology proficiency. The lack of technological capability among business actors has been identified as a factor contributing to difficulties in registering their products (Nugrahenti et al., 2021). This finding is consistent with research indicating that insufficient information technology skills hinder business actors during online registration processes (Ningrum, 2022). Providing guidance and support to business actors throughout the online registration process can serve

as an alternative solution to overcome these obstacles, enabling them to register their products independently. Based on Figures 2 and 4, UKOT accounted for the highest number of product submissions and a substantial proportion of incomplete documents, averaging 90%. Therefore, the discussion will focus on the UKOT group.

3.2.2 Compliance Profile within UKOT

Among the four required documentation aspects—administration, quality, efficacy/safety, and labeling—quality and labeling documents were most frequently incomplete. Labeling incompleteness often occurred because businesses prioritized marketing strategies to boost sales, designing visually attractive labels that did not comply with regulatory requirements. Research by Nurcahyani and Wahyudi (2024) found that 54% of 100 food MSMEs in Surabaya failed to comply with labeling regulations, while 33% did not include labels at all. Interviews with business operators revealed that these violations stemmed from internal factors, such as a lack of awareness and understanding of the importance of labeling, as well as external factors including market competition, regulatory complexity, associated costs, and regulatory ambiguity. (Nurcahyani & Wahyudi, 2024).

Meanwhile, the incompleteness of quality documentation was linked to the complexity of quality requirements, which not all UKOT could meet due to inadequate or incomplete laboratory facilities for product testing. The study showed that out of 98 UKOT in Central Java, only 5 UKOT, or approximately 5%, were able to fulfill all aspects of CPOTB. Sixty-three UKOT (64%) only met the requirements of CPOTB Stage I, while 26 UKOT (27%) had not yet met any of the CPOTB aspects (Suwarni et al., 2022). However, this study emphasizes the importance of quality documentation, as labeling deficiencies are not considered rigid requirements and may be included as supplementary notes in product approval if the other three aspects are met.

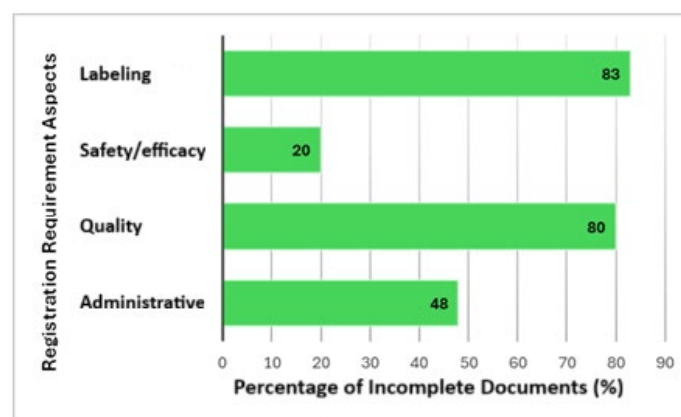


Figure 5. Compliance Profile within UKOT

This study highlights the diverse challenges faced by business actors in registering herbal medicines for stunting prevention in Indonesia from 2021 to 2023. The findings indicate that fulfilling administrative, safety, efficacy, and quality requirements remains a significant obstacle in obtaining marketing authorization, particularly regarding the provision of high-quality data. Nevertheless, compliance with these requirements is essential to ensure product

safety, quality, and efficacy. Therefore, interventions should focus on providing practical education for businesses, such as targeted awareness programs emphasizing quality documentation and continuous coaching clinics. The development of pocket guides illustrating registration procedures and requirements, supplemented with document samples, is also recommended to facilitate compliance.

This study provides an initial overview of the level of compliance with traditional medicine registration documents, which has not been previously investigated. However, the study has limitations in providing an in-depth explanation of the challenges causing incomplete registration documents. The primary limitation is the absence of survey or interview methods with business actors as a data collection approach. Therefore, the analyzed data are limited to information obtained from the product registration database, which does not comprehensively capture the root causes of the challenges faced by business actors. Further research using qualitative approaches (survey and interview methods) is necessary to complement these findings and provide a more thorough understanding. Additionally, measuring the impact of accelerating marketing authorization for herbal medicinal products (HMP) aimed at stunting prevention is required to assess its effect on reducing stunting rates as part of an evaluation process.

4. Conclusion

This study demonstrated an increase in the number of herbal medicinal product submissions for stunting prevention in Indonesia during the 2021–2023 period, reflecting a growing awareness among business actors of the importance of product registration. Nevertheless, significant challenges persist in meeting documentation requirements, with incompleteness rates ranging from 75% to 80%. The highest rate of incompleteness was observed in the UKOT group, ranging from 88% to 91%. This is likely due to a limited understanding of regulations, as well as constraints in human resources and technology.

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