

Evaluation of Traditional Medicine Label Compliance Based on CPOTB: Post-Market Surveillance in the Working Area of BPOM Kediri

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ABSTRACT

Introduction. Traditional medicines are widely used in Indonesia, but their expanding circulation poses regulatory challenges in ensuring product safety, quality, and accurate consumer information. Labeling is a critical risk management tool and a key indicator of compliance with Good Manufacturing Practices for Traditional Medicines (CPOTB) within risk-based post-market surveillance systems.

Aim. This study aimed to assess the conformity of traditional medicine labeling with the implementation of Good Manufacturing Practices for Traditional Medicines (CPOTB) within the working area of BPOM Kediri as part of a risk-based post-market regulatory strategy.

Method. This applied observational study employed a descriptive cross-sectional design. Data were obtained from post-market surveillance activities through sampling of 30 traditional medicine products collected from pharmacies, herbal shops, modern retailers, and traditional markets within the BPOM Kediri jurisdiction during 2023–2025. Label conformity was evaluated using a CPOTB-based checklist in accordance with BPOM Regulation No. 25 of 2021. Data were analyzed descriptively to identify compliance profiles and dominant non-compliance categories.

Result. A total of 30 findings of non-compliance were identified from 30 product samples, demonstrating an increasing trend over the three-year period. The most frequent non-compliance indicators were excessive or misleading claims (30.0%), absence of batch or lot numbers (26.7%), and absence or misuse of marketing authorization numbers (23.3%). These findings indicate potential risks related to consumer protection, product traceability, and regulatory assurance.

Conclusion. Post-market surveillance of traditional medicines in the BPOM Kediri region during 2023–2025 revealed persistent and increasing labeling non-compliance primarily involving excessive claims, missing batch/lot numbers, and absent or inconsistent marketing authorization numbers highlighting the need to prioritize these elements as high-risk indicators in risk based surveillance, implement targeted corrective actions for recurrent offenders, and strengthen inter-regional regulatory coordination to ensure effective enforcement and consumer protection.

Keywords: traditional medicine, labeling, CPOTB, post-market surveillance, BPOM Kediri

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INTRODUCTION

Traditional medicines constitute an integral component of Indonesia's healthcare system and continue to experience increasing utilisation in line with strong community interest in natural-based health products. This growth reflects not only cultural acceptance and accessibility, but also a global trend toward complementary and traditional medicine use in preventive and curative contexts. However, the expanding circulation of traditional medicines in the national market presents both opportunities and regulatory challenges. The inherent variability of natural raw materials, differences in production standards, and the diversity of product claims may pose potential safety and quality risks if these products are not manufactured, distributed, and communicated in accordance with regulatory provisions. In this regard, the World Health Organization (WHO) continues to emphasise that the use of traditional and herbal medicines must be accompanied by robust

regulatory oversight to ensure product safety, quality, and rational use within the community (WHO, 2025).

Within the framework of drug and food regulation, labeling and packaging information are recognised as essential tools for risk management. Product labels act as formal communication media between manufacturers and consumers, providing critical information that supports safe and rational product use. Labeling functions not only to identify a product but also to convey essential safety, usage, and legal information. Incomplete, inaccurate, or unclear label content particularly regarding product composition, indications, dosage and directions for use, contraindications, side effects, storage instructions, batch identification, and marketing authorization numbers has the potential to increase the risk of misuse, reduce user safety, and undermine product quality assurance during distribution. Accordingly, compliance with labeling requirements has been identified as a key compliance indicator in post-market surveillance systems worldwide, especially for herbal and traditional medicinal products (Jayasinghe et al., 2022; Kashuri & Yanuar, 2025).

As the regulatory basis in Indonesia, the National Agency of Drug and Food Control (Badan POM) has established Regulation No. 25 of 2021 concerning the Implementation of Good Manufacturing Practices for Traditional Medicines (CPOTB). This regulation reinforces that the scope of CPOTB extends beyond production activities and encompasses comprehensive quality assurance systems, including labeling governance as an integral component of product quality and regulatory compliance. Appropriate, accurate, and complete labeling is therefore mandated as evidence that traditional medicinal products circulating in the community have fulfilled safety, quality, and regulatory information standards (BPOM, 2021). More recently, Indonesia has strengthened its regulatory framework through the implementation of risk-based surveillance, which places labeling and product information as priority supervision components in protecting consumers and supporting public health (BPOM, 2024).

Despite the availability of regulatory frameworks and ongoing supervisory efforts, several recent studies have reported that labeling non-compliance remains prevalent in traditional medicine products. Empirical findings in the past five years have documented issues such as exaggerated or unsupported claims, absence of critical safety information, missing batch and production identification, lack of storage instruction, and incomplete manufacturer identity (Amekyeh et al., 2024; Pratiwi & Rahmawati, 2025; Roziman et al., 2024). Furthermore, some traditional medicine products were reported to legally possess marketing authorization yet still failed to present complete and accurate labeling elements, indicating a gap between formal authorization and real-world compliance performance. These findings underline the need to strengthen post-market regulatory controls, especially through systematic evaluation of labeling conformity as part of a risk-based surveillance framework.

This regulatory concern is highly relevant to the surveillance context in the working area of BPOM Kediri. The region is characterised by an active circulation of traditional medicines distributed through pharmacies, drug outlets, herbal shops, modern retailers, and traditional markets. Such diverse distribution channels increase the likelihood of variability in labeling practices and present challenges for ensuring consistent compliance. Conducting a structured evaluation of labeling compliance in this region is therefore essential to obtain an empirical overview of the actual conditions in the field, identify dominant non-compliance patterns, and generate evidence that can support targeted regulatory actions, guidance to manufacturers, and strengthened consumer protection efforts.

Despite the establishment of CPOTB regulations and the implementation of risk-based post-market surveillance in Indonesia, empirical evidence specifically evaluating traditional medicine labeling compliance as an indicator of CPOTB performance at the regional level remains limited. Most existing studies report general non-compliance issues or focus primarily on product safety, without systematically linking labeling conformity to risk management functions and regulatory decision-making in post-market control. Moreover, there is a lack of applied research examining labeling non-compliance patterns across diverse distribution channels and their implications for risk-based surveillance prioritization, particularly within the BPOM Kediri jurisdiction. Therefore, a targeted evaluation of labeling compliance is needed to provide evidence-based support for strengthening post-market regulatory strategies and enforcement effectiveness.

METODE

This study is a descriptive observational conducted through direct observation and documentation of information on product packaging, using a label compliance checklist developed based on BPOM Regulation No. 25 of 2021 on the Implementation of CPOTB. The assessment focused on the completeness and clarity of key information (e.g., product identity, composition, indications, dosage/directions for use, warnings, side effects, contraindications, marketing authorization number, expiry date, storage instructions, and manufacturer identity). The evaluation results were recorded as compliant/non-compliant per item, and then analyzed descriptively to present the proportion of fulfillment for each label component and dominant patterns of non-compliance. This checklist-based and descriptive reporting approach is consistent with label/packaging evaluation studies in various settings for herbal and traditional products (Jordan et al., 2023). To ensure consistency and reliability in the evaluation of labeling compliance, the checklist used in this study was supported by an inter-rater reliability mechanism. The checklist was developed operationally based on BPOM Regulation No. 25 of 2021, with each item defined using clear, observable, and dichotomous criteria (e.g., present/absent, compliant/non-compliant) to minimize subjective interpretation.

During the study, assessments were performed independently using a standardized checklist format. In cases of ambiguity or borderline compliance, final decisions were reached through controlled discussion with direct reference to the relevant regulatory provisions. Through standardized indicator formulation, assessor training, and structured clarification procedures, the checklist demonstrated adequate reliability, ensuring that labeling compliance assessments were consistent, reproducible, and grounded in regulatory criteria.

The subject of this research is finished packaged traditional medicine products circulating at distribution facilities within the BPOM Kediri working area (e.g., pharmacies, drug/herbal shops, modern retail, and traditional markets). Samples were selected purposively to represent a variety of products and distribution points, with inclusion criteria that packaging must be intact and label information legible, thus enabling an objective assessment of labeling compliance using a checklist instrument. This approach aligns with common evaluation methods used in applied studies of herbal/traditional medicine labels, which employ purposive sampling of finished products and visual inspection tools to assess packaging and label details against regulatory requirements (Amekyeh et al., 2024).

HASIL DAN PEMBAHASAN

Finding

This study analyzed post-market surveillance data obtained from traditional medicinal products circulating in the working area of BPOM Kediri. Sampling activities were conducted across various distribution facilities, including pharmacies, herbal shops, drug stores, modern retail outlets, and traditional markets, as part of routine regulatory surveillance. Accordingly, the findings presented below should be interpreted as **indicative observations derived from field surveillance**, rather than as representative estimates of overall labeling compliance. This approach aligns with global and regional surveillance strategies that emphasize field-based monitoring to evaluate real-world regulatory compliance of herbal and traditional medicinal products (Amekyeh et al., 2024; Pratiwi & Rahmawati, 2025).

A total of 30 traditional medicinal products were assessed during the surveillance period from 2023 to 2025 using a structured labeling checklist based on CPOTB requirements. From these samples, 30 indicative findings of labeling non-compliance were identified, suggesting that labeling may remain a relevant regulatory concern within the surveillance context. An upward pattern in the number of non-compliance findings was observed over the three-year period, with 8 findings in 2023, 10 in 2024, and 12 in 2025. While not intended to demonstrate prevalence, this pattern indicates recurring labeling issues that warrant regulatory attention. Similar tendencies have been noted in other national and international surveillance reports of herbal and traditional medicinal products (Kashuri & Yanuar, 2025; Roziman et al., 2024).

The most dominant labeling non-compliance category identified was excessive or inappropriate therapeutic claims, which accounted for 9 findings (30.0%). These claims often extended beyond

approved indications or suggested exaggerated benefits that were not supported by regulatory authorization. Such misleading or exaggerated claims are widely recognized as a critical risk because they may influence irrational product use and misinform consumers, as highlighted by several recent global regulatory reviews on herbal and complementary medicine products (Jayasinghe et al., 2022; Kashuri & Yanuar, 2025; WHO, 2025).

The second most frequent non-compliance finding was the absence of batch or lot numbers, observed in 8 products (26.7%). Batch identification plays an essential role in product traceability, quality monitoring, and implementation of recall processes when safety or quality defects are identified. The absence of batch numbers indicates weaknesses in quality assurance systems, which is consistent with the findings of recent research demonstrating that labeling traceability indicators are often poorly implemented by certain herbal product manufacturers (Edo et al., 2024).

The third major non-compliance finding was the absence or misuse of marketing authorization numbers (NIE), identified in 7 products (23.3%). This category represents a serious regulatory concern because the marketing authorization number is a key indicator of product legality, regulatory approval, and compliance with safety and quality requirements. Circulation of products without valid authorization may pose risks to consumer safety and undermine regulatory trust. Studies in both national and international contexts similarly highlight legal non-compliance as a significant and recurrent problem in traditional and herbal medicine markets (BPOM, 2024; Pratiwi & Rahmawati, 2025).

Other less frequent but still relevant labeling issues included absence of expiration dates (6.7%), missing manufacturer identity (6.7%), faded or poor-quality printing (3.3%), and inconsistencies between label information and declared composition (3.3%). Although these categories occurred less frequently, they remain significant from a regulatory perspective. Missing expiration dates may compromise consumer safety by masking product stability risks, while incomplete manufacturer identity reduces accountability and complicates enforcement processes. Poor label durability and inaccurate information also reflect deficiencies in manufacturing quality systems, as emphasized in previous scholarly and regulatory literature (Arafah, 2024; Sharma et al., 2024).

Table 1. Summary of Traditional Medicine Label Non-Compliance Findings (2023–2025)

Non-Compliance Parameter	2023	2024	2025	Total	Persentase (%)
Excessive product claims	2	3	4	9	30,0
Missing batch/lot number	2	2	4	8	26,7
Missing/fake NIE	0	3	4	7	23,3
Missing expiry date	0	2	0	2	6,7
Missing manufacturer ID	2	0	0	2	6,7
Easily faded labeling	1	0	0	1	3,3
Label composition mismatch	1	0	0	1	3,3
Total	8	10	12	30	100

Overall, these indicative findings suggest that labeling remains a key focus area in post-market surveillance of traditional medicines in the BPOM Kediri working area. While the results are not intended to represent overall compliance levels, they provide practical regulatory signals to inform risk-based surveillance prioritization, targeted enforcement, and guidance for manufacturers and distributors (Gambo et al., 2025; Jayasinghe et al., 2022). Strengthening post-market labeling surveillance remains an essential strategy to improve traditional medicine safety, regulatory discipline, and consumer trust.

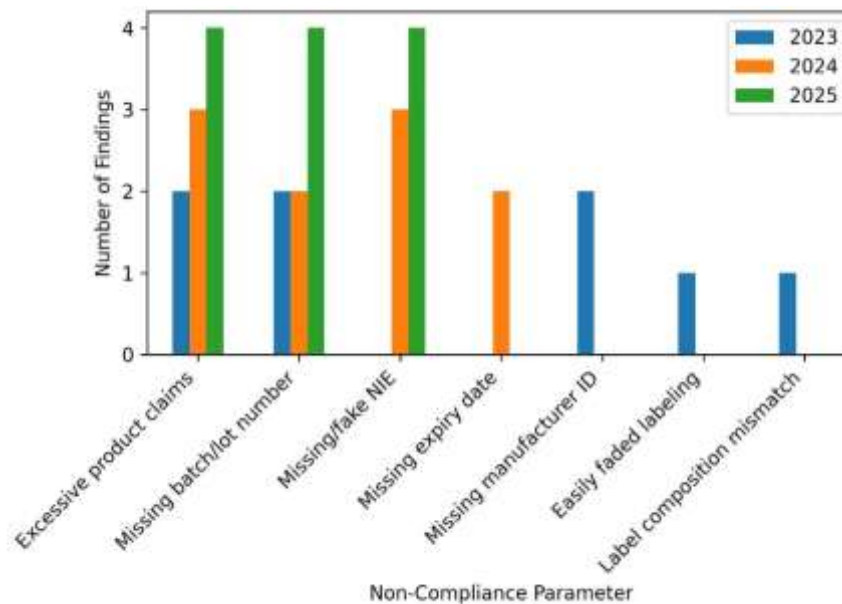


Figure 1. Traditional Medicine Label Non-Compliance Findings (2023–2025)

Pembahasan

The findings of this post-market surveillance study reaffirm that labeling remains one of the most critical and persistent regulatory challenges in the circulation of traditional medicinal products. The predominance of excessive or unsubstantiated therapeutic claims observed across products distributed in the BPOM Kediri region reflects a systemic weakness in ensuring the accuracy, integrity, and scientific accountability of information presented to consumers. Such claims are not merely technical deviations from regulatory standards; rather, they represent a significant public health concern. When consumers are exposed to exaggerated claims, they may overestimate the therapeutic benefits of traditional medicines, delay seeking appropriate medical care, or use products inappropriately, potentially resulting in adverse health outcomes. These findings are consistent with international evidence demonstrating that misleading or unverified claims remain among the most frequently identified labeling violations in herbal medicinal products and dietary supplements across diverse regulatory settings (Amekyeh et al., 2024; Vojvodić et al., 2025).

From a regulatory perspective, the persistence of excessive claims highlights challenges in both pre-market control and post-market enforcement mechanisms. While regulatory frameworks generally require that claims be supported by scientific evidence or traditional use documentation, enforcement gaps may arise due to limited resources, fragmented distribution networks, or insufficient deterrent effects of sanctions. The findings of this study align with global regulatory perspectives emphasizing that labeling must be scientifically verifiable, transparent, and non-misleading to support rational consumer decision-making and protect public health (Jayasinghe et al., 2022). Strengthening claim verification processes, including closer alignment between approved product dossiers and labels encountered in the market, is therefore essential to reduce misleading information and improve regulatory credibility.

Another key finding relates to the high frequency of products lacking batch or lot numbers, indicating substantial weaknesses in traceability systems. Batch identification is a cornerstone of quality assurance for pharmaceutical and traditional medicine products, as it enables systematic monitoring of production consistency, facilitates efficient product recalls, and supports corrective and preventive actions when quality or safety issues arise. The absence of batch or lot numbers

suggests inadequate implementation of documentation integrity and traceability requirements as mandated under CPOTB (BPOM, 2021). This deficiency is particularly concerning because traceability is not simply an administrative formality but a critical safety mechanism that ensures accountability throughout the supply chain, from manufacturing to distribution and retail.

Inadequate traceability undermines the regulator's ability to respond effectively to adverse events, contamination incidents, or product quality deviations. Moreover, it limits the capacity to identify responsible manufacturing entities and hampers enforcement actions. Previous studies have reported similar patterns, where deficiencies in labelling related traceability components were strongly associated with broader weaknesses in manufacturers' quality management systems, including poor documentation practices and limited internal quality oversight (Edo et al., 2024; Hossain et al., 2022). These findings suggest that labeling non-compliance related to batch identification may serve as an early indicator of deeper systemic issues within manufacturing operations.

Equally critical is the issue of missing or incorrectly declared marketing authorization numbers (NIE). Marketing authorization represents a fundamental indicator of regulatory legitimacy, confirming that a product has undergone evaluation for quality, safety, and labeling compliance prior to market entry. Products circulating without valid authorization or bearing falsified NIE numbers constitute serious regulatory and legal violations. Such practices not only expose consumers to unverified and potentially unsafe products but also undermine trust in the regulatory system and distort fair market competition. Within the framework of risk-based regulatory oversight, violations related to marketing authorization are categorized as high-risk and warrant priority enforcement actions, as outlined in BPOM Regulation No. 10 of 2024 (BPOM, 2024).

The persistence of unauthorized or improperly labeled products, as also reported in previous national studies Pratiwi and Rahmawati (2025), highlights the need for strengthened coordination across regulatory jurisdictions and supply chain actors. Given that many non-compliant products may originate outside the immediate BPOM Kediri working area, effective inter-regional information sharing and joint enforcement mechanisms are essential to prevent such products from repeatedly entering and persisting in local markets. This finding reinforces the importance of adopting a holistic, system-based approach to post-market surveillance that extends beyond localized inspections.

Other labeling deficiencies identified in this study, although less frequent, remain highly relevant from both regulatory and public health standpoints. Missing expiration dates undermine consumer confidence regarding product stability and safety throughout the product's shelf life and obscure potential risks related to product degradation. The absence of manufacturer identity information weakens accountability mechanisms, complicates regulatory follow-up actions, and limits the ability to trace responsibility in the event of quality or safety incidents. Furthermore, faded printing and inconsistencies between label information and declared composition indicate inadequate quality control over labeling materials, printing processes, and final product release procedures. Such deficiencies increase the risk of misinformation, product misidentification, and improper use by consumers (Bernardo Gonzaga Figueiredo Faria, 2024).

These observations are consistent with recent literature indicating that labeling quality problems are frequently linked to insufficient manufacturing oversight and weak compliance culture within the traditional medicine industry (Roziman et al., 2024). In this context, labeling deficiencies should be interpreted not as isolated technical errors but as reflections of broader organizational and systemic shortcomings, including limited management commitment to regulatory compliance and inadequate implementation of quality assurance principles.

Collectively, the findings of this study demonstrate that labeling assessment should not be viewed solely as an administrative requirement, but rather as a strategic regulatory tool that provides valuable insight into overall compliance performance. Labeling quality is closely interconnected with manufacturing standards, documentation reliability, traceability systems, and corporate governance. In line with WHO guidance and evolving international regulatory practices, labeling compliance remains a critical determinant of consumer safety and an essential focus of risk-based post-market surveillance for traditional and herbal medicinal products (Vojvodić et al., 2025).

From a regulatory policy perspective, the results of this study provide strong justification for prioritizing targeted interventions addressing key labeling weaknesses. These interventions include

strengthening controls over therapeutic claims through more rigorous pre-market evaluation and intensified post-market enforcement, enhancing verification mechanisms for marketing authorization numbers, and improving traceability documentation practices at the manufacturing and distribution levels. Additionally, sustained regulatory education and targeted guidance for manufacturers, distributors, and retail actors are essential to foster better understanding and consistent implementation of labeling obligations under CPOTB.

Ultimately, strengthening labeling compliance is expected not only to reduce recurrent non-compliance but also to support broader regulatory objectives, including enhanced consumer protection, improved regulatory credibility, and the creation of a safer and more transparent traditional medicine market in Indonesia. These efforts are particularly important as the utilization of traditional medicines continues to expand and plays an increasingly significant role in community health, thereby necessitating robust and adaptive regulatory oversight to safeguard public trust and public health outcomes.

KESIMPULAN

Based on post-market surveillance conducted on 30 traditional medicine products distributed within the BPOM Kediri region during the period 2023–2025, this study concludes that labeling remains a critical and persistent area of non-compliance. A total of 30 findings of non-compliance were identified, with a clear increasing trend observed over the three-year period. The most prevalent deficiencies included excessive or misleading therapeutic claims, absence of batch/lot numbers, and absence or inconsistency of marketing authorization numbers (NIE). These deficiencies represent significant regulatory concerns, as they may undermine consumer protection, compromise product traceability, and weaken legal assurance for products circulating in the market.

To address these issues, this study recommends several short-term and operational regulatory priorities. First, labeling elements related to therapeutic claims, batch identification, and marketing authorization numbers should be designated as high-risk indicators within risk-based post-market surveillance and prioritized for routine field inspection. Second, targeted corrective actions, including focused guidance and compliance notifications to manufacturers and distributors with recurrent labeling deficiencies, should be implemented. Third, strengthened inter-regional coordination is required, particularly for non-compliant products originating from outside the BPOM Kediri jurisdiction, to ensure consistent enforcement and follow-up actions. Collectively, these measures provide a practical intervention framework to enhance labeling compliance, reinforce CPOTB implementation, and support the safe and responsible circulation of traditional medicinal products.

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