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Proactive Risk Governance for Pharmaceutical Adulteration in Traditional Medicines: Evidence from Indonesia's 2022–2025 Recalls

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Abstract: Pharmaceutical adulteration in traditional medicines poses a persistent public health threat, particularly in countries with weak regulatory infrastructure. This study investigates the scale, trends, and governance failures contributing to the presence of undeclared pharmaceutical substances (Bahan Kimia Obat, BKO) in Indonesian herbal medicines between 2022 and early 2025. Using qualitative document analysis of official recall reports issued by the Indonesian Food and Drug Authority (Badan POM), the study identified a sharp increase in BKO cases through 2024, followed by an abrupt decline in 2025. Findings reveal not only a diversification in adulterant types—such as corticosteroids, anti-obesity drugs, and psychiatric agents but also strategic targeting of consumer expectations. Regulatory weaknesses include the absence of traceability systems, insufficient pre-market testing, and unclear licensing accountability. This study recommends structural reforms such as mandatory product serialization, third-party certification, and strengthened enforcement linked directly to manufacturers. The findings highlight the need for proactive, risk-based governance and coordinated stakeholder action to prevent recurrence and protect consumer safety.

Keywords: traditional medicines, pharmaceutical adulteration, regulatory surveillance, risk governance

1. INTRODUCTION

The global demand for traditional and herbal medicines continues to grow, with approximately 80% of the world's population depending on these products for primary healthcare. However, their perceived safety is often misleading, as cases of contamination, species substitution, and chemical adulteration with synthetic pharmaceuticals are increasingly reported [1]. In Indonesia, the popularity of traditional herbal medicine (jamu) has remained high, yet the regulatory infrastructure struggles to keep pace with evolving safety threats. Regulatory gaps in pre-market testing, inconsistent post-market surveillance, and fragmented legal accountability expose the public to high-risk products [2]. As a result, health authorities and toxicologists face complex challenges in safeguarding consumer safety, especially when adulterants mimic pharmacological effects, making detection and attribution more difficult [3].

Despite increasing government attention, the persistence of pharmaceutical adulterants in herbal products suggests limitations in current enforcement strategies. While recall mechanisms and routine lab testing exist, they are predominantly reactive. Moreover, the regulatory model remains centered on product outcomes rather than supply chain transparency or license-holder accountability

[4]. This illustrates a clear gap in the design of preemptive regulation that incorporates digital surveillance, serial batch tracking, and manufacturer risk profiling elements already adopted in some global pharmaceutical systems. In Indonesia's case, there is limited research that connects empirical recall data with systemic analysis of governance architecture. Without this synthesis, policymaking risks becoming episodic and data-poor.

Previous studies have mapped adulteration trends in China, India, and Malaysia, showing that undeclared pharmaceutical agents are commonly found in herbal treatments marketed for weight loss, sexual enhancement, and pain relief [5]. Supplementary testing methods (STMs), including chromatography and spectroscopy, have proven effective in early detection but remain underutilized in many developing nations. While some research has addressed the toxicology of such adulterants [6], few have contextualized these findings within broader governance frameworks. International regulatory models are converging toward lifecycle approaches and proactive risk management, yet implementation remains inconsistent [7]. The Indonesian setting rich in herbal usage but weak in traceability offers a critical case for such inquiry.

The urgency of addressing this issue stems not only from consumer safety concerns but also from international trade implications. Several countries, including Canada and Thailand, have reported Indonesian herbal products with banned pharmaceutical ingredients, undermining the credibility of national regulatory bodies [8]. This has prompted calls for ASEAN-wide harmonization of herbal product governance and digital traceability mechanisms [9]. Moreover, the rise of online and cross-border markets exacerbates enforcement challenges, enabling illicit products to bypass traditional checkpoints [10]. In this context, fragmented national enforcement becomes a global liability, especially when consumer demand for quick-acting herbal remedies remains high.

The novelty of this study lies in its integration of multi-year empirical recall data from Indonesia with a regulatory analysis perspective, offering both descriptive insights and systemic critique. By examining the trends in bahan kimia obat (BKO) adulteration from 2022 to 2025, and aligning them with policy lapses and enforcement gaps, this research provides a diagnostic tool for understanding why current approaches fail to deter repeat violations. Unlike earlier studies that focus either on product analysis or legal theory, this study bridges both to offer actionable recommendations for structural reform [11]. Furthermore, it highlights the evolution of adulterant types and the strategic behavior of manufacturers, aspects underexplored in Southeast Asian literature.

Therefore, the aim of this study is to examine the pattern, frequency, and diversity of BKO findings in Indonesian herbal medicines over the last four years, and to identify regulatory weaknesses that allow such practices to persist. By doing so, this research seeks to propose a roadmap for governance reform based on traceability, accountability, and risk-based enforcement. The findings are expected to inform policymakers, regulators, and scholars working on traditional medicine governance, pharmaceutical policy, and public health law in emerging economies. This study contributes not only to academic literature but also to regulatory strategy development in a region experiencing both herbal medicine growth and quality control failure [12].

2. MATERIALS AND METHODS

2.1. Study Design

This research employed a qualitative exploratory design using document-based content analysis. The study aimed to systematically examine the patterns, substances involved, and governance gaps related to pharmaceutical adulteration in traditional medicines in Indonesia over a four-year period.

2.2. Data Sources

Primary data were obtained from official recall announcements, inspection reports, and regulatory publications issued by the Indonesian Food and Drug Authority (Badan POM) between January 2022 and March 2025. These documents are publicly available and were accessed through BPOM's official website. Each report contained verified information on product identity, the presence of undeclared pharmaceutical substances (BKO), manufacturer names, and regulatory responses.

2.3. Inclusion and Exclusion Criteria

This study included traditional medicine products (jamu) that were explicitly cited in official recall documents issued by the Indonesian Food and Drug Authority (BPOM) for containing undeclared pharmaceutical substances (BKO), limited to documents published between January 2022 and March 2025, and products that were marketed within Indonesia. Products were excluded if they were classified as cosmetics or dietary supplements, or if the recall documentation lacked clear evidence of BKO content or verification by BPOM.

2.4. Data Extraction and Classification

Data from each document were extracted manually and compiled into a structured spreadsheet. The extracted variables included year of recall, product name, name of manufacturer or distributor, specific BKO identified, and type of regulatory action taken. The adulterants were classified into pharmacological categories such as corticosteroids, stimulants, anti-obesity agents, antihistamines, and psychotropics.

2.5. Analytical Framework

The analysis focused on descriptive interpretation through thematic coding and classification of regulatory trends. The study did not involve any laboratory verification or quantitative statistical testing. Visualizations including line graphs, frequency tables, and conceptual diagrams were developed to support interpretation and highlight longitudinal shifts in adulteration patterns. This approach allowed for the identification of systemic regulatory failures and provided a basis for governance-based policy recommendations.

2.6. Ethical Considerations

As this study relied entirely on publicly accessible secondary data published by a government agency, no ethical approval was required. However, data were used strictly for academic and analytical purposes, and all attributions to BPOM have been preserved to maintain transparency.

3. RESULTS AND DISCUSSION

3.1. Trends in BKO Adulteration (2022-2025)

The prevalence of synthetic pharmaceutical adulterants, commonly referred to as BKO, in Indonesian traditional medicines continues to pose a critical regulatory and public health challenge. Between 2022 and 2024, the number of BKO-containing herbal products reported by BPOM rose

sharply from 22 to 61, before declining abruptly to 6 in early 2025, as shown in Figure 1. While this drop may be interpreted as regulatory success, it also raises questions regarding surveillance intensity or evasion tactics by manufacturers. This trend mirrors similar findings in other countries where weak regulatory enforcement has enabled long-term proliferation of adulterated traditional products, particularly in decentralized or informal markets [13]. Such inconsistencies suggest that snapshot recall data alone may not fully capture systemic risks.

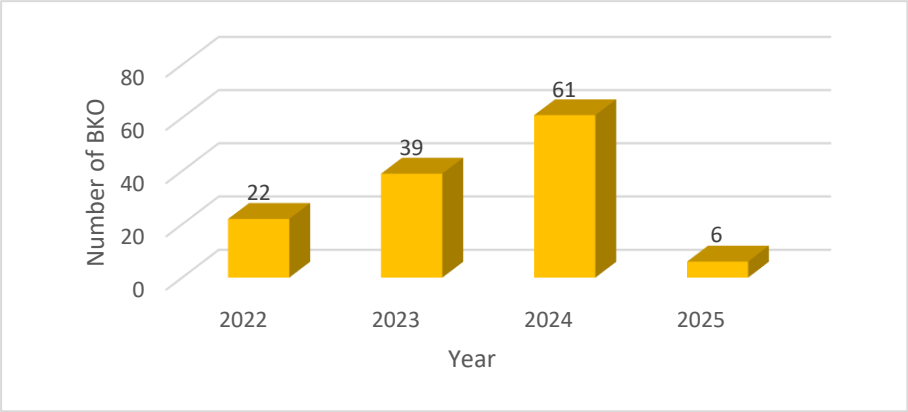

Figure 1. The number of distinct BKO detected in herbal products

3.2. Diversification of Pharmaceutical Substances

The types and quantities of BKO identified during the 2022–2025 period, as shown in Table 1. More concerning than the overall case count is the diversification of pharmaceutical adulterants over time. By 2024, BPOM identified nine distinct BKO substances in circulation, including anti-obesity agents, antihistamines, and psychiatric drugs, which extended far beyond commonly flagged adulterants like sildenafil or sibutramine [14]. This trend reflects not only a growing technical capacity to manipulate herbal formulations, but also an intentional shift in product design by unscrupulous producers to cater to evolving consumer expectations [15]. The strategic use of illicit substances, such as sibutramine analogues or antidepressants like fluoxetine, demonstrates that producers are imitating the pharmacological effects of regulated drugs to boost perceived efficacy [16]. This mimicry of modern pharmacology not only misleads consumers but also introduces significant toxicological risk due to unpredictable interactions among undeclared active ingredients [17].

Table 2. Types of pharmaceutical substances (BKO) detected

Year	Types of Pharmaceutical Substances (BKO) Detected	Quantity	References
2022	Dexamethasone, Paracetamol, Phenylbutazone, Sildenafil, Sibutramine, Tadalafil	6	[18]
2023	Dexamethasone, Sildenafil, Tadalafil, Yohimbe, Paracetamol, Ephedrine HCl, Pseudoephedrine HCl, Phenylbutazone, Sibutramine	9	[19]
2024	Sildenafil, Tadalafil, Sibutramine, Fluoxetine, Orlistat, Chlorpheniramine Maleate, Phenylbutazone, Promethazine HCl, Miconazole Nitrate	9	[20]
2025	Sibutramine, Dexamethasone, Paracetamol, Natrium Diclofenac, Bisacodyl	5	[21]

Source: Compiled by the author from BPOM public reports (2022–2025)

3.3. Therapeutic Indications of Adulterated Products

Analysis of recall reports shows that BKO-laced herbal products are most often marketed for lifestyle-related indications such as weight loss, sexual stamina, joint pain, fatigue, and vitality. These product claims suggest that producers are deliberately targeting consumer expectations for rapid results, often using undeclared chemicals to simulate fast-acting effects. Table 2 summarizes the most common indications linked to products containing BKO.

Table 2. Indications of traditional medicines containing BKO

No.	Indications of Traditional Medicines	Pharmaceutical Adulterants
1.	Weight loss	Sibutramine, Orlistat, Bisacodyl
2.	Sexual stamina	Sildenafil, Tadalafil, Yohimbe, Ephedrine HCl
3.	Pain/inflammation relief	Paracetamol, Natrium Diclofenac, Dexamethasone
4.	Fatigue or general tonic	Fluoxetine, Chlorpheniramine Maleate, Pseudoephedrine HCl
5.	Joint or muscle health	Phenylbutazone, Natrium Diclofenac

3.4. Regulatory Gaps and Traceability Failures

The repeated detection of certain adulterants particularly sibutramine and dexamethasone across multiple years underscores persistent weaknesses in Indonesia's pharmaceutical regulatory system. A similar pattern was reported in Taiwan, where corticosteroids and nonsteroidal drugs were repeatedly found in traditional pain and inflammation remedies [22]. Despite ongoing recall efforts, the absence of a digital traceability infrastructure and mandatory batch-level serialization hinders the ability to monitor product movement from manufacturing to retail. In contrast to lifecycle regulatory models adopted in countries like China and the EU, Indonesia's oversight remains predominantly reactive, relying on end-product testing rather than upstream control. This fragmented approach enables systemic evasion and delays the detection of adulterated products until post-market surveillance is initiated, creating a wide regulatory blind spot.

The dramatic decline in BKO detections in early 2025 presents an ambiguous outcome. While the drop may suggest improved compliance by manufacturers, it could just as plausibly be attributed to reduced sampling frequency or more sophisticated adulteration and evasion techniques [23]. Surveillance inconsistencies have been similarly observed in other jurisdictions, where inadequate sampling protocols led to underreporting of adulterated herbal products [24]. Malaysian and Indian case studies demonstrate that high-profile crackdowns often produce only temporary improvements, after which violations re-emerge in new forms or markets [25]. In the Indonesian context, the sharp reduction in detections during early 2025 might reflect not a cleaner market, but regulatory blind spots and enforcement resource gaps. Therefore, assessing enforcement success should not rely solely on the number of products recalled but should also account for the recurrence and diversification of violations over time [26].

A notable insight is the alignment of BKO usage with lifestyle-driven therapeutic goals. Substances most frequently detected were designed to imitate pharmacological effects targeting sexual stamina, weight loss, pain relief, and mood enhancement, revealing a deliberate pattern of illicit formulation [27]. This trend reflects a global shift in consumer behavior, where the boundaries between traditional remedies and biomedical drugs are increasingly blurred by overlapping

indications and expected outcomes [25]. These blurred lines are often exploited by manufacturers who introduce undeclared synthetic substances into herbal formulations to fulfill rapid consumer demand, particularly in markets where such practices go unchecked [28]. Consequently, regulatory responses must move beyond product-centered surveillance to address the socio-cultural motivations behind consumer preference for quick-fix natural alternatives. This includes integrating public education, targeted demand-side policies, and stricter ethical controls over advertising and labeling [29].

Despite the growing complexity of BKO cases, regulatory tools remain outdated. For instance, Indonesia still lacks a product serialization or digital traceability system for herbal medicines. In contrast, countries with high BKO detection have increasingly adopted barcode-based or blockchain-based tracking systems to trace supply chains and prevent unauthorized market entry [30]. Without such systems, enforcement becomes reactive and labor-intensive, enabling illegal products to bypass checkpoints. Incorporating end-to-end traceability would transform post-market surveillance into a proactive risk governance mechanism, closing critical gaps in distribution oversight. The absence of a traceability system in Indonesia's herbal medicine supply chain creates multiple blind spots from production to retail, as illustrated in Figure 2, allowing adulterated products to bypass regulatory checkpoints and reach consumers undetected.

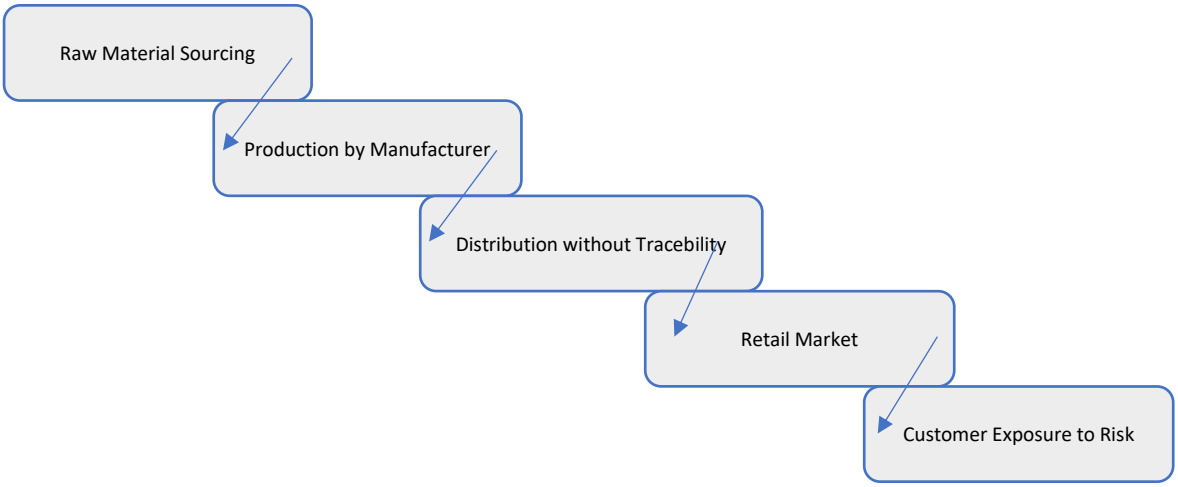

Figure 2. The risk flow of adulterated product without traceability system

3.5. Cross-border and Licensing Challenges

Reports from authorities in Thailand and Canada have identified Indonesian traditional medicines containing banned pharmaceutical substances, exposing cross-border safety risks and undermining regulatory credibility. Many such products lacked valid registration or were sold under counterfeit authorization numbers. This reveals structural flaws in the licensing system, including the delegation of legal responsibility to distributors rather than manufacturers, which has diffused accountability. In the absence of regional harmonization and digital oversight, Indonesia remains vulnerable to domestic loopholes and international liabilities. Addressing this challenge requires harmonized standards, regionally coordinated pharmacovigilance, and stronger ASEAN-wide enforcement cooperation [31].

An additional systemic flaw is evident in licensing and registration fraud. Many adulterated products either lacked valid marketing authorization or were sold under counterfeit numbers. This exposes weaknesses in pre-market screening and ongoing license holder accountability. These challenges mirror global regulatory fragmentation, where lack of harmonized standards and premarketing controls have been linked to uncontrolled circulation of adulterated herbal products [32]. In drug compounding contexts, similar gaps in centralized tracking and adverse event reporting have facilitated consumer harm and regulatory evasion. In Indonesia, the recent allowance for third-party distributors to hold licenses without production oversight may exacerbate this loophole, enabling a diffusion of responsibility across the supply chain.

The findings of this study clearly identify regulatory fragmentation, insufficient pre-market filtering, and ineffective traceability systems as core problems underlying the persistent presence of BKO in traditional medicines. Although BPOM performs periodic testing, the lack of upstream control mechanisms such as verified raw material sourcing, GMP audits, and mandatory serialization leaves the market vulnerable to systemic adulteration. Evidence from China supports the value of supplementary testing methods (STMs), which enhance early detection by combining chromatography, spectrometry, and molecular techniques such as DNA barcoding [5]. Similarly, a recent study highlighted how combining DNA metabarcoding with phytochemical analysis significantly improves authentication accuracy for herbal medicines [33]. Moreover, handheld near-infrared spectroscopy and advanced molecular screening techniques are now available for rapid field-level detection, helping regulators act before products reach consumers [34]. A robust early-warning system that leverages real-time recall data, consumer complaints, and laboratory flags would enable more targeted, risk-based inspections. While this study offers strong empirical and policy insights, it is not without limitations. The analysis relies primarily on publicly disclosed data from BPOM, which may underrepresent the actual prevalence of BKO usage due to limited sampling frequency and geographic coverage. This issue mirrors broader critiques of herbal medicine surveillance systems, which often lack national-level consistency and integration [35]. In countries such as Australia, DNA metabarcoding and omics-based techniques have revealed widespread mislabelling in herbal products, even those with formal registration [36].

Table 3. Gaps in implementation of key regulatory measures

No.	Proposed Reform Strategy	Current Implementation Status	Rationale / Expected Benefit
1.	Mandatory product serialization	Not implemented	Track and authenticate product batches to prevent illegal substitution
2.	Independent third-party lab testing before market entry	Not required under current BPOM regulation	Ensure unbiased safety validation before products reach the market
3.	Centralized digital traceability system	Not available	Enable real-time supply chain monitoring and intervention
4.	Direct manufacturer accountability in licensing	Partially delegated to distributors	Close accountability gaps and reduce regulatory evasion
5.	Integration of demand-side education in regulation	Absent from current BPOM programs	Address sociocultural drivers behind risky consumer behavior

3.6. Policy Recommendations and Stakeholder Roles

Addressing the persistent issue of BKO adulteration requires coordinated action across multiple stakeholder groups. Regulatory authorities, particularly BPOM, should implement mandatory product serialization and establish a centralized digital traceability system to monitor supply chains in real time. Pre-market safety validation must be strengthened through independent third-party laboratory certification to ensure unbiased testing before products reach consumers. Manufacturers must be held legally accountable for product content, with enforcement mechanisms that include regular GMP audits and stricter licensing tied directly to production oversight. Public health interventions should target consumers through sustained risk communication campaigns that build awareness about the dangers of "fast-acting" traditional remedies and promote demand for safe, certified products. Academic institutions and laboratories can support regulatory enforcement by advancing rapid detection technologies, such as portable spectroscopy and DNA barcoding, which can be used in field inspections. Finally, policymakers should update and harmonize regulatory frameworks with ASEAN standards, including imposing stricter penalties on repeat violators and closing legal loopholes that allow distributor-based evasion. These combined efforts would establish a more proactive and integrated risk governance model capable of reducing BKO prevalence and protecting consumer safety.

4. CONCLUSION

This study demonstrates that pharmaceutical adulteration in Indonesian traditional medicines remains a persistent and evolving public health issue, marked by an increasing frequency and diversification of undeclared substances such as sibutramine and dexamethasone between 2022 and 2024. Although a decline in detection was noted in early 2025, it likely reflects reduced surveillance rather than improved compliance. The findings highlight critical regulatory weaknesses, including the absence of traceability systems, lack of independent pre-market testing, and insufficient accountability mechanisms. The deliberate use of adulterants to mimic therapeutic effects underscores a growing market-driven risk. To address these challenges, the study recommends strengthening regulatory governance through digital traceability, third-party certification, and targeted stakeholder roles. These insights offer a policy-relevant framework for enhancing risk prevention and regulatory modernization in the traditional medicine sector.

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