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Review Article

Regulatory Reform and Policy Mapping in Indonesia's Traditional Medicine, Health Supplement, and Cosmetic Sectors

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Abstract

This study systematically analyzed Indonesia's regulatory reforms for traditional medicines, health supplements, and cosmetics (TMHSC) issued between 2020 and 2024. The objective was to map the scope, distribution, and policy orientation of the 35 regulations enacted by the Indonesian Food and Drug Authority (BPOM) within the framework of the National Medium-Term Development Plan (RPJMN 2020–2024). A qualitative policy analysis was employed, combining document analysis, thematic coding, and comparative benchmarking with frameworks from the ASEAN, European Union (EU), and Organisation for Economic Co-operation and Development (OECD). The findings show that 25 regulations were directed toward strengthening regulatory services, nine targeted compliance and Good Manufacturing Practices (GMP), and one supported research and innovation through preclinical testing standards. This distribution reflects a policy trajectory that prioritizes service delivery and compliance assurance, while progressively integrating evidence-based approaches to research and innovation. A comparative analysis revealed a strong alignment with ASEAN harmonization initiatives and an incremental adoption of international benchmarks, such as ISO 22716 for cosmetics and the WHO GMP guidelines for herbal medicines. Overall, Indonesia's TMHSC regulatory transformation demonstrates a balanced and adaptive governance model that safeguards public health, promotes innovation, and enhances regional policy coherence. The results provide practical implications for policymakers, particularly BPOM and ASEAN member states, in developing regulatory frameworks that effectively balance consumer protection, innovation enablement, and market competitiveness within the TMHSC sectors.

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INTRODUCTION

Traditional medicines, health supplements, and cosmetics (THMSC) have historically served as pillars of public health systems, embodying the diverse sociocultural identities of global populations, including those in Indonesia. Over the past decade, these sectors have undergone a rapid paradigm shift, fueled by biotechnological breakthroughs, heightened consumer literacy, the proliferation of digital commerce, and an increasing emphasis on personalized and sustainable healthcare[1-3]. Advances in analytical chemistry have particularly revolutionized quality assurance, enabling the precise detection of adulterants and more rigorous product standardization[4]. Concurrently, the post-pandemic emergence of health-conscious digital consumers has intensified the demand for transparent, evidence-based claims and ethical branding[5]. These shifts have redefined herbal and health-related products as vital instruments for environmental

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sustainability and inclusive economic growth, particularly within ecologically sensitive forest-frontier communities[6-8]. Indonesia, as a biodiversity hotspot with profound indigenous knowledge systems and a maturing regulatory landscape, is uniquely positioned to lead the Global South in shaping safe, innovation-driven health markets. This trajectory aligns with the World Health Organization (WHO) Global Report on Traditional and Complementary Medicine, which emphasizes the need for robust regulatory frameworks to ensure the safety, efficacy, and formal integration of traditional medicines into national health systems[9].

Despite this progress, persistent safety challenges continue to plague the TMHSC sectors, primarily driven by economic incentives for illicit adulteration, substitution, and dilution[10]. Botanical products are frequently compromised by mislabeling or the use of inferior species, a phenomenon well-documented in global authenticity studies of ginseng[11]. Furthermore, the dietary supplement market remains vulnerable to the inclusion of banned pharmacologically active substances, such as sibutramine, which poses severe cardiovascular risks despite its prevalence in unregulated weight-loss products[12]. The rapid expansion of e-commerce, combined with historically weak enforcement, has created oversight gaps that pose a threat to consumer safety[13]. The cosmetics sector faces similar complexities, particularly in integrating nanotechnology. While enhancing functional efficacy, it raises critical questions concerning dermal penetration and systemic toxicity[14,15]. Growing concerns over the irritation and toxicity associated with synthetic compounds have further accelerated the demand for plant-based alternatives[16]. While the European Union has pioneered advanced frameworks for high-risk ingredients, such as those derived from algae, persistent issues, including heavy metal contamination and a lack of harmonized international standards, highlight the urgent need for consistent, enforceable global oversight[17].

In a proactive effort to mitigate these risks, BPOM initiated a comprehensive regulatory reform agenda for 2020–2025. This transformation leverages risk-based classification, evidence-based claim evaluations, and the digitalization of registration and surveillance systems to align with ASEAN and EU standards. These reforms are designed to protect public health while catalyzing research-driven industrial competitiveness. Globally, similar shifts toward regulatory agility in digital and energy sectors have expanded market access and accelerated technology adoption, though outcomes often vary based on governance quality[18,19]. While Latin American reforms suggest that unregulated marketization can deepen health inequities, European models demonstrate that public investment in innovation infrastructure bolsters long-term resilience[20,21]. Evidence further indicates that administrative reforms prioritizing collaboration and performance orientation, rather than mere market logic, are most effective at stimulating public sector innovation[22]. Indonesia's balanced governance model thus seeks to protect consumers while fostering a competitive environment for innovation.

Significant gaps remain in the literature regarding the conceptualization and institutionalization of regulatory innovation in developing Southeast Asian nations. Existing research has primarily focused on pharmaceutical frameworks in high-income countries, leaving the unique governance challenges of traditional and herbal medicines in resource-limited contexts underexplored[4,23]. This review addresses this void by systematically mapping the evolution of Indonesia's TMHSC regulatory framework through document analysis, thematic coding, and international benchmarking. For Indonesia, the central challenge lies in designing frameworks that ensure safety and scientific validation without marginalizing indigenous knowledge or cultural practices. Recent regional studies suggest that digital infrastructure and culturally grounded governance can bridge these gaps[24].

Furthermore, the rise of ESG-oriented regulation in Southeast Asia underscores the need for adaptive, context-specific frameworks that strike a balance between inclusivity and safety[25]. Comparative data from countries like Nigeria and Malawi highlight the risks associated with weak enforcement, underscoring the importance of the current Indonesian reforms[26]. Insights from other disruptive sectors also suggest that adaptive tools, such as regulatory sandboxes, may be highly applicable to TMHSC oversight[27]. By positioning Indonesia as a reference model for evidence-based governance, this review extends the global discourse on adaptive regulation in low- and middle-income countries.

Building upon this background, the present paper provides a critical examination of Indonesia's evolving TMHSC regulatory landscape, focusing on its scientific rationale, legal foundations, and contributions to regional integration. Beyond its academic contributions, the study offers tangible policy value by mapping 35 key regulations issued between 2020 and 2024. These findings help policymakers identify strategic priorities, such as streamlining GMP certification for micro, small, and medium-sized enterprises (MSMEs) and developing innovation-supportive instruments, like regulatory sandboxes. This is the first systematic mapping of TMHSC regulatory reforms in Indonesia for this period, providing essential insights for health governance. The results directly inform the strategic agenda of the National Medium-Term Development Plan

(RPJMN 2020–2024) and reinforce Indonesia's commitment to aligning with ASEAN and OECD benchmarks. Ultimately, this review contributes a replicable framework for other nations seeking to establish balanced, innovation-enabling regulatory systems for traditional and complementary health products.

MATERIALS AND METHODS

Materials

This review employed a qualitative policy analysis framework to assess the regulatory landscape within Indonesia's TMHSC sector between 2020 and 2024. The study focused on a corpus of 35 specific regulations promulgated by BPOM. To ensure a robust dataset, inclusion criteria required that all selected documents directly address the oversight of TMHSC products, were enacted within the timeframe of January 2020 to June 2024, and demonstrate alignment with the objectives of RPJMN 2020–2024. The analyzed primary sources comprised formal BPOM regulations (*Peraturan BPOM*), administrative decrees (*Keputusan Kepala BPOM*), and comprehensive technical guidelines (*Pedoman Teknis*). All materials were retrieved from the BPOM official regulatory portal and subsequently cross-referenced with the national legal database to guarantee authenticity and categorical completeness.

Methods

Regulatory mapping and document analysis

The document analysis phase was structured to systematically extract policy objectives, specific regulatory provisions, and corresponding enforcement mechanisms[28]. Each regulation was meticulously screened against the inclusion criteria, resulting in a finalized corpus of 35 items. These documents were subsequently mapped into three distinct categories derived from RPJMN strategic priorities and international standards: research and innovation, regulatory services and public administration, and compliance and industry supervision. Thematic coding was executed manually using a hybrid inductive and deductive approach to distinguish recurring policy orientations and reform trends. To maintain high inter-coder reliability, two researchers independently coded the entire corpus across iterative rounds; any discrepancies in coding were resolved through consensus meetings. This process focused on technical provisions and enforcement strategies, with the categorization further validated against the WHO Global Benchmarking Tool 2021, which offers a maturity-level framework for regulatory systems[29].

Data analysis

The synthesized mapping results underwent descriptive analysis to quantify the distribution of regulations across the defined categories, while thematic analysis was employed to interpret qualitative shifts in the regulatory environment. This interpretation focused on emerging trends, including ASEAN harmonization, the implementation of digital oversight systems, and the integration of biotechnology[30]. The rigorous path from initial document retrieval to final coding validation is summarized in **Figure 1**, which delineates the stepwise analytical flow applied throughout this review to ensure methodological transparency.

RESULTS AND DISCUSSION

Regulatory profiles and strategic mapping

The analysis of the regulatory landscape between 2020 and 2024 revealed that BPOM issued 35 active instruments governing traditional medicines, health supplements, quasi-drugs, and cosmetics (**Table I**). This legislative corpus, comprising 16 decrees and 19 formal regulations, reflects a multifaceted approach to striking a balance between technical oversight and procedural modernization. During this period, 15 earlier mandates were either revoked or revised to ensure the regulatory framework remained responsive to contemporary industry needs, resulting in the 35 distinct documents currently under review. The comprehensive profile of these regulations, disaggregated by commodity, year of issuance, and legal type, is detailed in **Table II**.

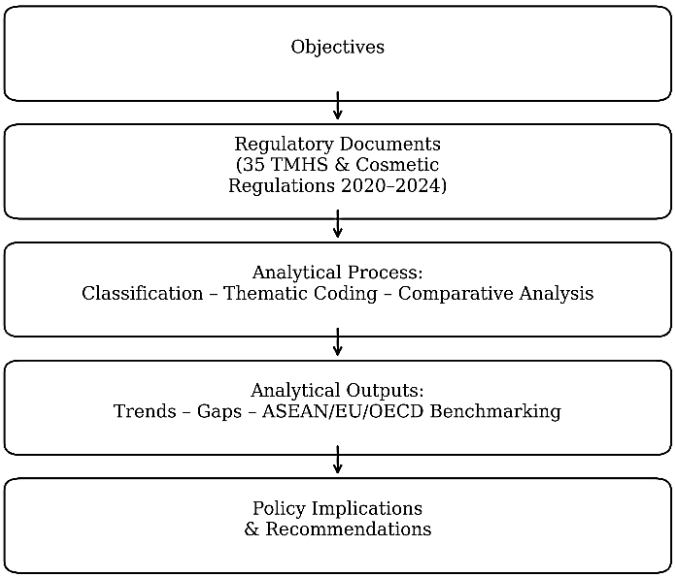

Figure 1. Flow of analysis applied in this review.

Table I. Comprehensive inventory of BPOM regulations on traditional medicines, health supplements, and cosmetics (2020–2024).

No	Regulation Number	Title of Regulation	Year	Category	Type
1	Decree No. HK.02.02.1.2.12.20.1417	Determination and Monitoring of Melatonin as a Special Purpose Health Supplement	2020	HS	Decree
2	Regulation No. 31 of 2020	Amendment to Regulation No. 25/2019 on GMP for Cosmetics	2020	C	Regulation
3	Regulation No. 4 of 2021	Monitoring Mechanism for Side Effects of Traditional Medicines and Health Supplements	2021	TM, HS	Regulation
4	Decree No. HK.02.01.1.2.03.21.125	Technical Instructions: Issuance of Recommendations for Cosmetic Notification Applicants	2021	C	Decree
5	Decree No. HK.02.01.1.2.03.21.143	Technical Guidelines for Alpha Hydroxy Acid (AHA) Control in Cosmetics	2021	C	Decree
6	Decree No. HK.02.02.1.2.12.21.468	Vitamin D (1000 IU – 4000 IU) as a Special Purpose Health Supplement	2021	HS	Decree
7	Regulation No. 14 of 2021	GMP Certification for Traditional Medicines	2021	TM	Regulation
8	Regulation No. 17 of 2021	Assessment Guidelines for Health Supplements Containing Probiotics	2021	HS	Regulation
9	Regulation No. 19 of 2021	Monitoring Follow-up Guidelines for TM, Q, HS, and Cosmetics	2021	TM, HS, C, Q	Regulation
10	Regulation No. 25 of 2021	Implementation of GMP for Traditional Medicine	2021	TM	Regulation
11	Regulation No. 33 of 2021	GMP Certification for Cosmetics	2021	C	Regulation
12	Regulation No. 8 of 2021	Permitted Cosmetic Preparations for Class B Cosmetic Industries	2021	C	Regulation
13	Decree No. HK.02.02.1.2.02.22.78	Side Effect Monitoring for TM and HS Distribution Permit Holders	2022	TM, HS	Decree
14	Decree No. 246 of 2022	Restricted Import Ingredients for TM, Q, Cosmetics, and Food (SME Focus)	2022	TM, Q, C	Decree
15	Regulation No. 17 of 2022	Amendment to Regulation No. 23/2019 on Technical Requirements for Cosmetic Ingredients	2022	C	Regulation
16	Regulation No. 19 of 2022	Guidelines for Health Supplement Claims	2022	HS	Regulation
17	Regulation No. 21 of 2022	Procedures for Cosmetic Notification Submissions	2022	C	Regulation
18	Regulation No. 3 of 2022	Technical Requirements for Cosmetic Claims	2022	C	Regulation
19	Regulation No. 31 of 2022	Technical Instructions for Gradual GMP Implementation for Traditional Medicines	2022	TM	Regulation
20	Regulation No. 32 of 2022	Criteria and Procedures for Health Supplement Registration	2022	HS	Regulation
21	Regulation No. 34 of 2022	Supervision of Advertising for Traditional Medicines, Quasi-Drugs, and Health Supplements	2022	TM, HS, Q	Regulation
22	Decree No. 479 of 2023	Amendments to Permitted Ingredients in Cosmetics	2023	C	Decree
23	Regulation No. 12 of 2023	Supervision of Cosmetic Manufacturing and Distribution	2023	C	Regulation
24	Regulation No. 16 of 2023	Supervision of the Distribution of TM, Q, and HS	2023	TM, Q, HS	Regulation
25	Regulation No. 17 of 2023	Cosmetic Product Information Document (CPID) Guidelines	2023	C	Regulation
26	Regulation No. 20 of 2023	Guidelines for Preclinical Pharmacodynamic Testing of Traditional Medicines	2023	TM	Regulation
27	Regulation No. 24 of 2023	Safety and Quality Requirements for Health Supplements	2023	HS	Regulation
28	Regulation No. 25 of 2023	Criteria and Procedures for Registration of Natural Medicines	2023	TM	Regulation
29	Regulation No. 29 of 2023	Safety and Quality Requirements for Natural Medicines	2023	TM	Regulation
30	Regulation No. 30 of 2023	Guidelines for Efficacy Claims in Natural Medicines	2023	TM	Regulation
31	Regulation No. 7 of 2023	Criteria and Procedures for Quasi-Drug Registration	2023	Q	Regulation
32	Decree No. 390 of 2024	Adoptive Parent Program Guidelines for Natural Medicine and Cosmetic SMEs	2024	TM, C	Decree
33	Regulation No. 10 of 2024	Labeling Requirements for Natural Medicines, Quasi-Drugs, and Health Supplements	2024	TM, HS, Q	Regulation
34	Regulation No. 16 of 2024	Contamination Limits in Cosmetics	2024	C	Regulation
35	Regulation No. 18 of 2024	Cosmetic Labeling, Promotion, and Advertising Guidelines	2024	C	Regulation

Note: TM: Traditional Medicine; HS: Health Supplement; C: Cosmetics; Q: Quasi-Drugs

Table II. BPOM regulatory output for traditional medicines, supplements, and cosmetics (2020–2024).

Commodity Category	2020	2021	2022	2023	2024	Total	RPJMN Classification
	R | D	R | D	R | D	R | D	R | D		
Traditional Medicine (TM)	0 | 0	2 | 0	1 | 0	4 | 0	0 | 0	7	1 Research; 6 Regulatory Services
Health Supplements (HS)	0 | 1	1 | 1	2 | 0	1 | 0	0 | 0	6	All Regulatory Services
Cosmetics (C)	1 | 0	2 | 2	3 | 0	3 | 1	2 | 0	14	5 GMP; 9 Regulatory Services
Quasi Drugs (Q)	0 | 0	0 | 0	0 | 0	1 | 0	0 | 0	1	Regulatory Services
Cross-Category Groups							
TM–C	0 | 0	0 | 0	0 | 0	0 | 0	0 | 1	1	GMP (MSME Foster Program)
TM–HS	0 | 0	1 | 0	0 | 1	0 | 0	0 | 0	2	Regulatory Services
TM–HS–C	0 | 0	1 | 0	0 | 0	0 | 0	0 | 0	1	Regulatory Services
TM–HS–Q	0 | 0	0 | 0	1 | 0	0 | 1	0 | 0	2	Regulatory Services
TM–Q–C	0 | 0	0 | 0	0 | 1	0 | 0	0 | 0	1	Regulatory Services
Total	1 | 1	7 | 3	7 | 2	9 | 1	2 | 1	35	1 Research; 25 Reg. Serv.; 9 GMP

Note: R = Regulation; D = Decree

To provide a more evaluative perspective beyond simple description, the data analysis involved a systematic categorization of these regulations based on the three strategic priorities of RPJMN 2020–2024. These priorities include research development, the optimization of regulatory services, and the enhancement of compliance through GMP. This mapping methodology facilitates a clear visualization of how regulatory actions align with overarching national policy objectives, promoting public health and safety.

A functional analysis of the 35 regulations revealed that the vast majority, comprising 25 instruments, were dedicated to enhancing regulatory services. These measures encompass critical areas, including product registration, claim substantiation, labeling requirements, safety thresholds, and robust post-marketing surveillance. In contrast, nine regulations were specifically designed to strengthen GMP compliance, focusing on certification standards and phased implementation frameworks for manufacturing facilities. Only one regulation was explicitly directed toward research development, focusing on preclinical pharmacodynamic testing guidelines for traditional medicines. This structured profiling indicates that Indonesia's regulatory reform is characterized by a strategic emphasis on service delivery and compliance assurance, while gradually incorporating evidence-based standards to support long-term innovation in the pharmaceutical and cosmetic sectors.

Regulatory mapping of TMHSC (2020–2024)

To evaluate the congruence between Indonesia's regulatory reforms and RPJMN 2020–2024, 35 identified TMHSC regulations were systematically mapped against three strategic pillars: research development, regulatory service improvement, and the enhancement of compliance through GMP. Each legal instrument was coded based on its core objectives and substantive provisions to ensure the categorization reflected its functional policy impact rather than mere administrative nomenclature. The analysis revealed that a significant majority of these regulations (n = 25) focused on optimizing regulatory services, encompassing product registration, claim substantiation, and post-marketing surveillance. Notably, the introduction of rigorous scientific requirements for probiotic assessment and health supplement claims aligns Indonesian governance with international benchmarks such as the Codex Alimentarius and ASEAN Guidelines. A second cohort of nine regulations focused on strengthening GMP compliance, addressing facility certification and manufacturing oversight in a manner that aligns with ISO 22716 and WHO GMP standards. Conversely, research development was represented by a singular, pivotal regulation: the 2023 guideline for preclinical pharmacodynamic testing. This guideline facilitates the transition of traditional formulations into scientifically validated phytopharmaceuticals, reflecting evidence-based trajectories seen in China and South Korea.

The synthesized data presented in **Table III** highlights a dual-oriented reform trajectory that balances stringent consumer safety with an enabling environment for industry innovation, particularly for MSMEs. This hybrid model parallels frameworks in the European Union and ASEAN, where regulation fosters market trust and regional harmonization while reducing procedural duplication through mutual recognition. Quantitative analysis of these reforms reveals that approximately 71% of BPOM's activities prioritize administrative efficiency and modernization, a strategy consistent with OECD "smart regulation" principles, which emphasize institutional agility and risk-based oversight. While research-oriented regulations currently constitute a smaller fraction (3%) of the total output, the emergence of preclinical standards

signifies a foundational shift toward translational research. Furthermore, the 26% of regulations dedicated to GMP underscore a proactive transition toward high-level quality governance and international alignment.

Table III. Regulatory mapping of TMHSC sector in Indonesia (2020–2024).

No.	Regulation (BPOM)	Focus Area	Regulatory Category	Strategic Policy Implication
1	No. 17/2021 Probiotic Claims	Strain-specific evidence & clinical trial substantiation.	Research & Innovation	Incentivizes R&D investment; aligns national standards with Codex/ASEAN frameworks.
2	No. 19/2022 Health Supplement Claims	Classification (Structure/Function, Maintenance, Risk Reduction).	Compliance & Oversight	Enhances market transparency and prevents deceptive marketing in the nutraceutical sector.
3	No. 23/2019 (Amended No. 17/2022)	Restriction of high-risk ingredients & nanomaterial oversight.	Public Health & Safety	Harmonizes standards with ASEAN/EU; ensures proactive monitoring of advanced materials.
4	Draft Regulation Biotech-based Cosmetics	Safety evaluation & mechanistic claim validation.	Emerging Technology	Establishes legal certainty for Halal Biotech; supports regional leadership in innovative cosmetics.
5	No. 12/2020 GMP for Traditional Medicines (CPOTB)	Facility standards & batch traceability.	Quality Assurance	Facilitates ASEAN Mutual Recognition Arrangements (MRAs); streamlines cross-border inspections.
6	Decree No. 390/2024 MSME Foster Program	Industry mentoring & capacity building.	Industrial Development	Promotes inclusive growth; integrates MSMEs into the National Health Resilience strategy.

Collectively, these findings illustrate that Indonesia's regulatory landscape has evolved into a sophisticated model that integrates market facilitation with rigorous scientific validation, thereby enhancing its competitive standing in the regional TMHSC market[31-35]. However, certain limitations must be acknowledged. This review relied exclusively on publicly available BPOM documents; potentially omitting nuances found in internal implementation reports. Furthermore, while the coding process involved independent validation by two researchers to mitigate subjectivity, the thematic analysis remains interpretive. Future research should consider longitudinal tracking or stakeholder interviews to provide a more holistic assessment of policy impacts. Despite these constraints, this analysis offers a robust empirical foundation for understanding Indonesia's ongoing regulatory transformation and its commitment to evidence-informed policymaking.

Regulatory analysis methodology

To address the research question concerning the reformation of Indonesia's regulatory landscape within TMHSC sector, this review utilized a comprehensive policy document analysis supplemented by thematic interpretation[30]. This methodological framework allowed for the systematic identification of recurring themes within regulatory texts, enabling a critical evaluation of these policies against national priorities and prevailing global regulatory shifts.

Regulatory reform in the Indonesian TMHSC sector is best conceptualized as a structured, staged evolution aimed at establishing a responsive and effective oversight framework[36]. This process has primarily involved the codification of rigorous standards for product registration, the scientific substantiation of health claims, and the mandatory implementation of GMP. These reforms mirror the foundational phases of regulatory strengthening seen in various international health systems, where consolidating oversight capacity is a prerequisite for subsequent technological innovation and global harmonization.

The significance of this trajectory is further reinforced by international precedents; for example, the historical expansion of the healthcare regulatory apparatus in the United States fundamentally reshaped both product oversight and the broader configuration of the national health system[37]. Similarly, Indonesia's current reforms indicate that regulatory evolution extends beyond mere administrative adjustments, reflecting a profound transformation in governance that integrates public health protection with industrial competitiveness and consumer confidence. From this vantage point, regulatory instruments function as essential levers for enhancing safety and quality by mandating technical compliance and certification. Recent directives from BPOM, spanning pharmacodynamic testing guidelines to specific probiotic claim substantiation, serve as tangible evidence of a strategic reorientation toward risk-based and evidence-informed governance within the sector.

Key regulatory updates in the traditional medicine sector: Evidence-base and quality standardization

The standardization of both raw materials and finished herbal products remains a significant barrier to the global acceptance of natural medicines, a challenge consistently highlighted in contemporary pharmaceutical research[38,39]. In Indonesia, the regulatory landscape has undergone significant maturation over the last twenty years to mitigate these concerns. A pivotal moment occurred in 2004 when BPOM, under Decree No. HK.00.05.4.2411 established a structural hierarchy for traditional medicines, classifying them into three distinct tiers: Jamu, Standardized Herbal Medicines (OHT), and Phytopharmaceuticals. This classification provided the first formal framework for differentiating herbal products based on their depth of scientific validation. The system was further refined by IFDA Regulation No. 25 of 2023, which imposed more rigorous criteria for each category to ensure consumer safety and product efficacy. Under this current mandate, Jamu refers to traditional formulations supported by longitudinal empirical use and community-based evidence, whereas Standardized Herbal Medicines must be substantiated by preclinical or early-stage clinical data demonstrating safety and therapeutic action. Phytopharmaceuticals represent the pinnacle of this hierarchy, requiring pharmaceutical-grade standards that encompass completed Phase III clinical trials, rigorous toxicological assessments, and exhaustive quality control protocols.

This stratified regulatory approach ensures that all-natural medicines, whether produced domestically, imported, or licensed, are subject to consistent scrutiny across all market pathways. Such evidence-based stratification carries profound implications for the industry, establishing a progressive path that encourages manufacturers to elevate their standards by transitioning from empirical formulations to scientifically validated phytopharmaceuticals, often through enhanced academic–industry collaborations. Furthermore, by embedding scientific validation as the cornerstone of regulatory approval, the government provides a credible mechanism to dismantle historical skepticism toward herbal therapies, thereby fostering consumer trust and facilitating the formal integration of these therapies into national healthcare delivery.

Notably, Indonesia is currently drafting new policies to incorporate selected herbal medicines into the national healthcare formulary, particularly for use in primary and community health services. This shift aligns Indonesia with global leaders in the sector, such as China, India, and South Korea, where sophisticated, multi-tiered regulatory systems have successfully enabled the coexistence of traditional medicine within modern biomedical frameworks[40,41]. By institutionalizing these evidence-based reforms, Indonesia is not merely preserving its vast ethnobotanical heritage but is actively positioning itself as a regional leader in herbal medicine governance. These strategic updates provide fertile ground for domestic innovation and international competitiveness, ultimately transforming Indonesia's biodiversity into high-value, validated therapeutic assets that strengthen both public health outcomes and national economic resilience.

Key regulatory updates in the health supplement sector: A rapidly growing domain in need of governance

The health supplement sector in Indonesia has undergone significant expansion, driven by an increasing consumer appetite for functional nutrition and microbiome-targeted interventions. This growth has necessitated a more sophisticated regulatory framework and robust scientific governance to address emerging complexities. In response, BPOM promulgated Regulation No. 17/2021, which provides specialized guidelines for assessing probiotic-based supplements. This regulation mandates rigorous requirements for claim substantiation, requiring strain-specific scientific documentation, human clinical trial data, and dose–response validation to ensure that any marketed benefits are both robust and reproducible. Unlike generalized nutritional claims, probiotic health claims must now be substantiated at the strain level, with specific physiological benefits (such as immunomodulation, gastrointestinal enhancement, or metabolic regulation) clearly demonstrated in human cohorts[42]. This shift effectively bridges a historical regulatory gap where generalized data often facilitated potentially misleading marketing strategies[43]. By enforcing strain-specific accountability, regulators have strengthened consumer protection against unverified products, thereby enhancing the overall reliability and safety of the probiotic marketplace[44,45].

Further refining this oversight, BPOM enacted Regulation No. 19/2022 regarding Health Supplement Claims, which established a formalized hierarchy for evaluating and classifying functional and structure–function claims. Under this framework, claims are categorized into three distinct tiers: basic structure/function claims, maintenance of normal physiological functions, and risk reduction claims, the latter of which are subjected to the most intensive level of evidentiary scrutiny. This regulation strictly prohibits the use of vague or therapeutic language and extends its oversight to include graphic symbols, taglines, and implied wording, ensuring that all marketing materials remain grounded in scientific reality.

Such reforms are integral to BPOM's strategic positioning of health supplements as complementary wellness tools rather than pharmacological substitutes. This rigorous evidentiary requirement incentivizes manufacturers to invest in high-quality clinical research and align their dossiers with international benchmarks, such as the Codex Alimentarius and the ASEAN Guidelines on Health Supplement Claims[46].

From a public health and economic standpoint, this evolving regulatory posture serves a dual purpose. First, it safeguards vulnerable demographics, particularly the elderly and those with chronic illnesses, from deceptive or exaggerated health expectations. Second, it cultivates a science-driven innovation ecosystem that rewards companies for generating high-quality evidence and practicing responsible communication. This increased regulatory predictability is a fundamental requirement for attracting both domestic and international investment into Indonesia's burgeoning nutraceutical industry. Ultimately, these updates reflect Indonesia's commitment to global best practices in functional food governance, prioritizing transparency, traceability, and consumer health literacy. By fostering a more accountable market, the current regulatory trajectory supports both scientific advancement and substantial commercial opportunities within a framework of clinical certainty.

Key regulatory updates in the cosmetics sector: Safety, innovation, and sustainability of innovative cosmetic products

The rapid progression of biotechnology within the cosmetics industry has catalyzed the development of advanced formulations incorporating stem cell-derived components, exosomes, peptides, and growth factors, all of which offer significant potential for skin regeneration, anti-aging, and aesthetic enhancement. However, these technological milestones present substantial regulatory hurdles, specifically concerning safety protocols, the substantiation of therapeutic claims, and the necessity for labeling transparency[47-49]. To navigate these complexities while maintaining consumer protection and market integrity, BPOM has initiated the drafting of a specialized regulatory framework for stem cell- and biotechnology-based cosmetics, effectively addressing a vital gap in the current oversight architecture.

This forthcoming regulatory framework is anticipated to enforce rigorous preclinical safety assessments, mandate that product claims be substantiated through mechanistic *in vitro* or *in vivo* studies, and require standardized labeling to provide clear information regarding the biological origin and functionality of ingredients. Such interventions are a direct response to prevailing issues regarding transparency and scientific validity, particularly for products marketed as "stem cell cosmetics" that frequently utilize conditioned media or extracts lacking functional cells and robust clinical evidence. By establishing minimum concentration thresholds for active ingredients, requiring validated mechanisms of action, and enforcing consistent terminology, the regulation seeks to mitigate deceptive marketing and bolster consumer confidence. This initiative reflects a broader global shift toward ethical and transparent cosmetic practices, paralleling the European Union's nanoparticle disclosure mandates[50] and the burgeoning trend of utilizing fermentation-based production to create sustainable, evidence-based cosmetic solutions[51]. By emphasizing scientific accountability, regulators serve as essential intermediaries that bridge the gap between marketing claims and actual product performance, thereby cultivating a more reputable and consumer-centric marketplace.

In formulating this framework, BPOM is expected to integrate international best practices, drawing from the standards of the EU Scientific Committee on Consumer Safety (SCCS) and the US FDA's guidance on human cell- and tissue-based products (HCT/Ps). Critical safety parameters currently under review include immunogenicity, systemic toxicity, genetic instability, and the risks of cross-species contamination, especially for ingredients derived from animal stem cells or unverified biotechnological platforms[52]. Aligning with these global benchmarks allows Indonesia to manage regulatory risks and facilitate international harmonization preemptively. Strategically, this regulation pursues two primary goals: safeguarding public health by ensuring regenerative claims are scientifically grounded and fostering responsible innovation through the creation of predictable pathways for research and development. This dual approach is particularly salient for Indonesia's objective to lead the regional market in halal biotechnology cosmetics, where oversight must blend ethical sourcing with rigorous quality assurance and transparency.

Furthermore, the framework is expected to introduce a regulatory sandbox model, which permits early-stage innovative products to enter the market under stringent monitoring. At the same time, their evidence portfolios are progressively developed, a strategy successfully implemented in South Korea and Japan to harmonize technological growth with safety requirements[53]. Ultimately, BPOM's proactive engagement in drafting these regulations represents a transformative phase

in Indonesia's cosmetic governance. By defining clear standards for innovation while addressing the inherent risks associated with disruptive biotechnologies, the agency enhances consumer protection and regulatory authority. This strategic positioning not only establishes Indonesia as a progressive regulator within the global cosmetic biotechnology arena but also enhances its capacity for sustainable market growth, investment attraction, and regional leadership[54].

Regulatory landscape and strategic challenges in the TMHSC sector

Indonesia's regulatory framework for traditional medicines and health supplements has demonstrated progressive alignment with regional harmonization efforts, specifically under the ASEAN Agreement on a Regulatory Framework for TMHS. While no single regulation explicitly codifies this transition, several recent instruments issued by BPOM exhibit substantial convergence with ASEAN standards regarding safety thresholds, product classification, and quality assurance[55]. This strategic commitment reinforces consumer protection while facilitating regional market integration by embedding national policies within the broader ASEAN architecture[56,57]. A primary example of this convergence is found in the CPOTB, which now align with ASEAN GMP standards in facility inspections and batch traceability. These harmonized requirements facilitate MRAs among member states, effectively reducing redundant inspections and enhancing regional market access.

Further harmonization is evident in the standardization of product claims through BPOM Regulations No. 19/2022 and No. 17/2021, which mandate rigorous scientific substantiation and prohibit misleading therapeutic assertions. These provisions align with the ASEAN TMHS Annex on Claims, prioritizing transparency and preventing consumer deception in health-related marketing. In the cosmetics sector, Indonesia has similarly integrated its standards with those of ASEAN and the European Union to address global supply chain complexities and high-risk ingredients. Regulation No. 23/2019, along with subsequent amendments such as Regulation No. 17/2022, incorporates outcomes from the ASEAN Cosmetic Scientific Body (ACSB), which utilizes EU provisions as scientific references. A notable regulatory shift was the prohibition of formaldehyde (previously permitted as a nail hardener) following toxicological assessments and post-marketing surveillance data shared across member states[58,59].

Indonesia has also adopted proactive measures concerning nanomaterials in cosmetics, such as nanoscale titanium dioxide and zinc oxide. These substances now require stringent safety assessments, including particle size disclosure and enhanced labeling, particularly when systemic absorption poses potential health risks[51,60]. By aligning national policies with international best practices, BPOM upholds a precautionary yet innovation-enabling approach that strengthens the global credibility of Indonesia's cosmetic industry[61]. From a strategic standpoint, ASEAN harmonization fulfills a dual role: enhancing public health through shared scientific rigor while fostering economic integration by reducing regulatory fragmentation[62]. This alignment unlocks export opportunities for standardized herbal products, leveraging Indonesia's rich tradition in natural medicine for global recognition[63]. Furthermore, harmonized standards support collaborative investments and joint clinical trials in the nutraceutical sector, positioning Indonesia as a leader in the Southeast Asian wellness landscape[63].

The integration of the ASEAN Cosmetic Directive (ACD) and TMHS guidelines into national law represents a significant shift toward regional regulatory convergence. This transition is formally reflected in BPOM Regulation No. 32 of 2019 and No. 17 of 2021, which ensure consistency in safety assessments and ingredient listings while maintaining regulatory sovereignty. Through participation in the TMHS Product Working Group (TMHS PWG), BPOM facilitates reciprocal data sharing and recognition of technical guidelines. These efforts align with the long-term vision of health security established by Law No. 17/2023 and Government Regulation No. 28/2024. Additionally, BPOM has introduced the Foster Parent Program for MSMEs (Decree No. 390/2024) to provide structured technical mentorship MSMEs[64]. By addressing technical expertise gaps, this program accelerates MSME growth and ensures the availability of safe, innovative traditional medicines and cosmetics, successfully bridging socio-economic development with public health objectives.

Global comparative insights and analysis

The analysis of global regulatory experiences within TMHSC sectors reveals a critical demand for harmonized, evidence-based frameworks to mitigate systemic safety risks, including product adulteration, undeclared active pharmaceutical ingredients, and the emerging toxicological challenges of nanotechnology. International organizations, specifically the

WHO, alongside regional bodies such as the European Union and ASEAN, have increasingly advocated for regulatory agility to strike a balance between rigorous consumer protection and facilitating cross-border trade and innovation[17]. Within this global context, Indonesia's regulatory landscape from 2020 to 2024 has undergone a strategic transformation characterized by digitalization, risk-based classification, and deeper harmonization within ASEAN. These shifts align with the benchmarks established in the OECD Regulatory Policy Outlook and World Bank reports, which suggest that adaptive governance is a prerequisite for sustaining both market competitiveness and public safety[65,66]. While the European Union has successfully utilized regulatory agility to foster innovation clusters, and some Latin American neoliberal reforms have struggled with market access inequities, Indonesia's hybrid approach appears anticipatory, integrating international policy lessons into its unique national framework.

The comparative evidence further suggests that Indonesia's reform trajectory offers a significant model for other low- and middle-income countries (LMICs) in the Global South, where market structures and governance capacities often differ from those in high-income nations. By positioning itself at the intersection of industrial facilitation, regional alignment, and robust consumer safeguards, Indonesia has emerged as a primary reference point for regulatory innovation within Southeast Asia[67,68]. This is further evidenced by the country's integration of sustainability-focused reforms, which address global environmental and labor standards, and have been positively linked to improved domestic safeguards and broader access to international supply chains[69]. Additionally, the implementation of digital oversight mechanisms, risk-based assessment frameworks, and the incorporation of financial innovations, such as Fintech, demonstrates how adaptive governance can simultaneously advance public health objectives and sustainable economic growth in emerging economies[70-72].

Historically, comparative research on regulatory evolution has focused almost exclusively on high-income jurisdictions, such as Japan, the United States, and the European Union, emphasizing data-driven pharmacovigilance and sophisticated post-market surveillance[48,50,52,73]. However, there is a notable scarcity of scholarly investigation into how these processes translate to resource-constrained environments, particularly in the context of hybrid product categories such as traditional medicines[74,75]. Indonesia's experience bridges this analytical gap by demonstrating that even in resource-limited settings, the integration of risk-based supervision and regional harmonization can create a viable and effective governance model. Ultimately, this comparative perspective serves as the interpretative foundation for Indonesia's hybrid governance, positioning it as a potentially scalable reference for other emerging economies seeking to modernize their regulatory oversight while maintaining economic vitality.

CONCLUSION

In summary, this research presents the inaugural systematic mapping of Indonesia's regulatory landscape regarding TMHSC throughout the transformative period of 2020 to 2024. By meticulously categorizing 35 distinct regulations into the functional domains of research and innovation, regulatory services, and industry compliance, the study benchmarks these advancements against international frameworks established by the WHO, OECD, and ASEAN. The primary novelty of this work resides in its detailed illustration of how a biodiversity-rich, middle-income nation has successfully architected an adaptive governance model. This approach strategically integrates comprehensive digitalization, risk-based classification, and regional harmonization to balance the dual priorities of safeguarding public health and fostering an environment that encourages innovation. Distinguishing itself from existing literature that predominantly focuses on high-income jurisdictions, this article underscores Indonesia's hybrid regulatory strategy as a viable and replicable paradigm for other emerging economies. It serves as evidence that regulatory systems in developing contexts can evolve from traditional, compliance-heavy oversight into sophisticated, innovation-enabling frameworks that hold significant global relevance.

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AUTHORS' CONTRIBUTION

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DATA AVAILABILITY

None.

CONFLICT OF INTEREST

The authors declared no conflict of interest related to this research.

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