

Tantangan regulasi dan strategi kebijakan untuk kosmetik berbasis sel punca di Indonesia

Mohamad Kashuri¹

¹ The Indonesian Food and Drug Authority, Indonesia

✉ mohamad.kashuri@pom.go.id

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Abstrak

Kosmetik berbasis sel punca semakin diminati di Indonesia karena diklaim memiliki efek regeneratif dan anti-penuaan. Namun, produk tersebut masih diatur dalam sistem notifikasi kosmetik umum yang belum memuat ketentuan khusus terkait validasi efikasi, evaluasi keamanan, maupun pengawasan etika. Ketiadaan regulasi yang spesifik berpotensi menimbulkan risiko bagi keselamatan konsumen serta melemahkan kredibilitas inovasi bioteknologi kosmetik. Oleh karena itu, studi ini bertujuan menganalisis secara kritis lanskap regulasi kosmetik berbasis sel punca di Indonesia, mengidentifikasi kesenjangan kebijakan, dan merumuskan rekomendasi strategis untuk membangun kerangka regulasi yang lebih kuat, etis, dan berbasis sains. Penelitian ini menggunakan pendekatan tinjauan literatur naratif terhadap 28 publikasi akses terbuka dan terindeks sejawat yang terbit pada 2020–2025. Sumber yang dianalisis meliputi artikel ilmiah, dokumen regulasi nasional, dan naskah kebijakan institusional terkait penerapan sel punca dalam kosmetik serta tata kelolanya dalam perspektif kesehatan masyarakat. Hasil tinjauan menunjukkan bahwa Indonesia belum memiliki klasifikasi regulasi khusus untuk kosmetik berbasis bioteknologi. Tidak terdapat kewajiban uji efikasi pra-pemasaran maupun pengungkapan asal dan proses pengolahan sel punca. Sebaliknya, negara seperti Korea Selatan dan Uni Eropa telah menerapkan kerangka regulasi komprehensif yang menjamin transparansi, keamanan, dan kepatuhan etis. Temuan ini menegaskan bahwa pendekatan regulasi Indonesia yang masih pasif berpotensi melemahkan perlindungan konsumen dan kurang responsif terhadap perkembangan bioteknologi. Untuk mengatasi kesenjangan tersebut, studi ini merekomendasikan pembentukan kategori khusus kosmetik berbasis sel punca, penerapan evaluasi keamanan dan efikasi secara wajib, serta pembentukan dewan penasihat ilmiah guna menyelaraskan regulasi nasional dengan standar dan praktik terbaik internasional.

Kata Kunci: Stem cel; Kosmetika; Regulasi; Kebijakan publik

Regulatory challenges and policy strategies for stem cell-based cosmetics in Indonesia

Abstract

Stem cell-based cosmetics are gaining popularity in Indonesia due to their regenerative and anti-aging properties. However, these products are still governed under a general cosmetic notification system that lacks specific provisions for efficacy validation, safety evaluation, and ethical oversight. The absence of clear regulations may pose significant risks to consumer safety and undermine the credibility of cosmetic biotechnology innovations. Therefore, this study aims to critically analyze the current regulatory landscape surrounding stem cell-based cosmetics in Indonesia, identify key policy gaps, and propose strategic recommendations for establishing a more robust, ethical, and science-based regulatory framework. This study employed a narrative literature review approach, analyzing 28 peer-reviewed and open-access publications published between 2020 and 2025. The sources include scientific journals, national regulatory documents, and institutional policy papers that discuss the application of stem cells in cosmetics and their governance within public health frameworks. The review reveals that Indonesia does not yet have a distinct regulatory classification for biotechnology-based cosmetic products. There is no requirement for pre-market efficacy testing or for the disclosure of stem cell origin and processing. In contrast, countries such as South Korea and the European Union have implemented comprehensive regulatory frameworks that ensure transparency, product safety, and ethical compliance. The findings indicate that Indonesia's current passive regulatory approach may compromise consumer protection and fail to respond effectively to emerging biotechnological trends. To close these regulatory gaps, the study proposes the establishment of a specific category for stem cell-based cosmetics, the enforcement of mandatory safety and efficacy evaluations, and the creation of a scientific advisory board to align national regulations with international standards and best practices.

Keywords: Stem cells; Cosmetic; Regulation; Public policy

1. Introduction

The increasing demand for anti-aging and skin regeneration products has contributed to the global popularity of stem cell-based cosmetics. Consumers are increasingly attracted to these products because of



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their bioactive compounds that stimulate collagen production and restore dermal health. This trend has pushed cosmetic manufacturers to incorporate biotechnology-derived ingredients into their formulations, particularly plant and human-derived stem cell extracts (Gardiki et al., 2025). Stem cells in cosmetics are the active ingredients primarily utilized for their anti-aging effects on skin. Stem cell-derived products, such as exosomes and secretomes, possess multifaceted beneficial topical effects, including anti-inflammatory, antioxidant, and skin rejuvenating properties (Rodriguez et al., 2024). The mechanism of actions stem cells in skin rejuvenation is shown in **Figure 1** In Indonesia, this development faces significant regulatory ambiguity, particularly because the national cosmetics regulatory framework does not explicitly recognize or assess stem cell-based formulations under specialized safety or efficacy protocols (Putri et al., 2024). Consequently, consumers are exposed to products whose biological risks and efficacy claims remain unverified by the national authorities (Marliana & Israhadi, 2024).

Despite rapid advancements in regenerative dermatology, regulatory literature that harmonizes scientific innovation with legal safeguards is scarce. The Indonesian Food and Drug Authority (BPOM) primarily relies on the notification system under the ASEAN Cosmetic Directive (ACD), which lacks specific provisions for biotechnology-based or stem cell-derived products (Widjanarko & Anggoro, 2021). Moreover, the dichotomy between global regulatory practices, such as the European Union's strict prohibition on human stem cell use in cosmetics and South Korea's cosmeceutical recognition, exacerbates the policy vacuum in Indonesia (Yustina et al., 2024). These discrepancies raise concerns about the national authority's readiness to monitor and validate the influx of high-tech cosmetic innovations, which often escape traditional toxicology frameworks (Kim et al., 2021).

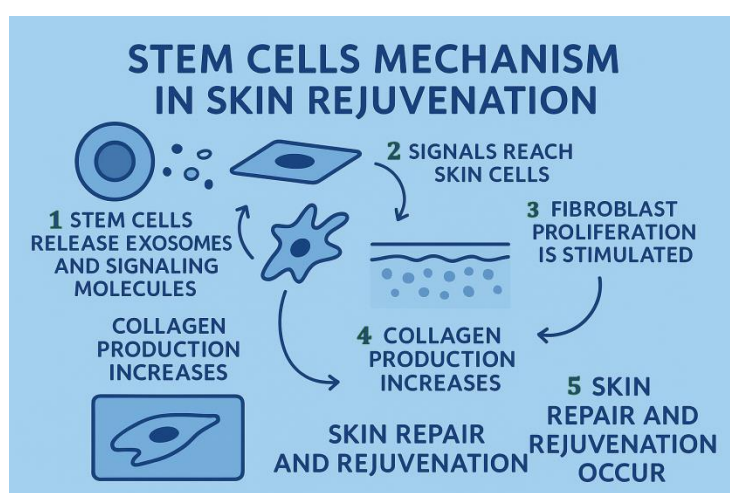


Figure 1 Illustration of Stem Cells Mechanism in Skin Rejuvenation (Source: Generate from AI Gemini, 2025)

Therefore, this study aimed to (1) review national and international regulations relevant to stem cell-based cosmetic product testing; (2) identify regulatory gaps and implementation challenges within BPOM's current system; and (3) formulate a science-based, adaptive, and consumer-oriented policy strategy that fosters both safety and innovation. These objectives are particularly significant in guiding Indonesia toward a more inclusive and evidence-based regulatory framework for a growing biotechnology landscape (Joeliaty & Ghaniyah, 2023).

In line with public policy theory articulated by Thomas R. Dye, which defines policy as “whatever governments choose to do or not to do” (Dye, 1972), the current absence of specific regulation can be viewed as a passive stance by the government. Such inaction creates regulatory ambiguity and reduces consumer confidence while offering no scientific basis for efficacy or safety. Thus, this research posits that the Indonesian government must move from regulatory silence to structured legal governance by aligning its cosmetic regulatory regime with contemporary scientific advancements (Lestari et al., 2023).

2. Method

This study examined regulatory gaps and strategies concerning stem cell-based cosmetic product testing in Indonesia using a narrative literature review (NLR) approach. The primary object of analysis is the regulatory framework of the Indonesian Food and Drug Authority (BPOM) which pertains to emerging cosmetic biotechnologies, particularly those that utilize stem cell-derived ingredients. The analysis extends to regulatory concepts applied in comparative countries, focusing on licensing pathways, efficacy validation, and consumer protection policies into the Indonesian context (Rosadi et al., 2024).

This study utilized a qualitative-descriptive design characteristic of the NLR methodology. The primary data consisted of peer-reviewed journals and policy documents that address stem cell cosmetics, regulatory frameworks, and ethical concerns. Secondary data sources include publications from Indonesian regulatory bodies, international best-practice guidelines, and doctrinal legal studies (Ardiantono et al., 2022). The criteria for selecting literature were based on relevance to at least one of the following three research keywords: stem cells, cosmetic regulation, and Indonesian policy. The databases accessed included PubMed, DOAJ, Google Scholar, and Indonesian national journals indexed by SINTA-1 and SINTA-2. Only studies published between 2020 and 2025 were included, and all the selected materials were available in open access formats.

The theoretical framework that anchors this study is Public Policy Theory introduced by Dye (1972). The theory posits that public policy is “what governments choose to do or not to do.” This is particularly relevant in this research because it helps analyze the absence of specific regulatory action in Indonesia regarding stem cell-based cosmetics as an implicit policy stance. This theory guides the interpretation of whether the government’s inaction is a result of strategic policy planning or a regulatory gap that must be addressed (Bestari, 2023).

The data collection process involved four main stages: (1) identification of relevant topics based on keywords; (2) screening titles and abstracts to apply inclusion criteria; (3) full-text analysis of selected articles; and (4) thematic categorization of regulatory, scientific, and ethical dimensions.

3. Result and Discussion

The integration of stem cells into cosmetics has created a novel intersection between biotechnology and dermatological aesthetics. Literature reveals that Plant-derived stem cells, particularly those extracted from *Malus domestica* and *Vitis vinifera*, are commonly used because of their antioxidant properties and potential to promote epidermal regeneration (Gardiki et al., 2025). These compounds are primarily used in anti-aging creams and sera to target dermal fibroblasts. In Indonesia, these products are marketed without a distinct labeling system that separates conventional products from biotech-based cosmetics (Rosadi et al., 2024). Figure 2 illustrates the typical production stages, from cell isolation to formulation integration, to support our understanding of how stem cell-derived ingredients are processed for cosmetic application.

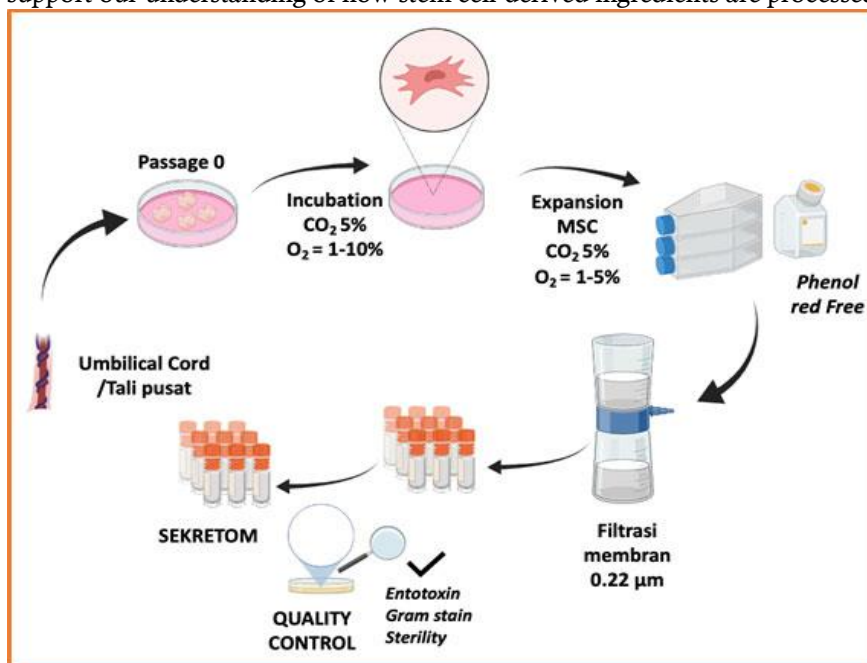


Figure 2 Production process of stem cell-based cosmetic ingredients (Source: Tristem Medika Indonesia, 2022)

Several studies have emphasized that while active compounds from stem cells are not considered therapeutic, their inclusion in cosmetics is promoted for regenerative purposes, such as reducing wrinkles, improving elasticity, and enhancing hydration (Kim et al., 2021). However, these claims are not supported by obligatory pre-market efficacy validation in the Indonesian BPOM system (Putri et al., 2024). Nevertheless, several stem cell-derived cosmetic products have already been approved by the BPOM in Table 1.

This unregulated context is particularly relevant when assessing the relationship between product marketing and regulatory oversight. The absence of a specific classification for stem cell-based cosmetics means that products with strong biological claims are regulated in the same manner as regular moisturizers or cleansers, creating regulatory loopholes (Marliana & Israhadi, 2024).

Table 1 Some stem cells cosmetic product marketed in Indonesia

No	Trademark	Industry	Notification
1	Stem Cellular Sleep Wrinkle Retinol Overnight Eye Cream	PT. Sephora Indonesia	NE51232000034
2	Stem Cellular CC Cream - Desert Glow	PT. Sephora Indonesia	NE51220300098
3	Stem Cellular 2-in-1 Cleanser	PT. Sephora Indonesia	NE51221200192
4	Stem Cellular CC Cream - Natural Glow	PT. Sephora Indonesia	NE51220300099
5	Stem Cellular CC Cream - Warm Glow	PT. Sephora Indonesia	NE51220300100
6	Stem Cellular Anti-Wrinkle Solutions	PT. Sephora Indonesia	NKIT220001000
7	Stem Cellular Anti-Wrinkle Overnight Retinol Serum	PT. Sephora Indonesia	NE51222000023
8	Stem Cellular Anti-Wrinkle Eye Treatment	PT. Sephora Indonesia	NE51222000024
9	Stem Cellular Anti-Wrinkle Moisturizer	PT. Sephora Indonesia	NE51222000025
10	Stem Cellular Anti-Wrinkle Overnight Retinol Serum	PT. Sephora Indonesia	NE51222000026
11	DJ Glow Erna Phyto Stem Cell Lotion	CV. Ibu Soraya Traditional Cosmetic	NA18240107362
12	Elfara Glow Phyto Stem Cell	CV. Ibu Soraya Traditional Cosmetic	NA18241900722

Indonesia adopts the ACD, which emphasizes product safety and labeling, but does not mandate specific toxicological or genomic testing for biotech ingredients (Widjanarko & Anggoro, 2021). While the ACD provides a regional standard, it has not been updated to integrate risk management frameworks for bioengineered compounds. Unlike the EU, which prohibits the use of human-derived stem cells in cosmetics, Indonesia does not define any ingredient exclusion based on the source origin (Yustina et al., 2024).

These regulatory conditions highlight the administrative gap between market activity and legal supervision. Products containing stem cell extracts are often positioned as premium skincare innovations but are not reviewed with a specialized regulatory lens. This contrasts sharply with countries such as South Korea and Japan, where stem cell-based ingredients fall under cosmeceutical guidelines that require evidence-based justification (Silvia et al., 2024). To further contextualize Indonesia's regulatory gap, Table 2 compares the classification and regulation of stem cell-based cosmetics in selected countries with mature biotechnology oversight systems.

Table 2 Global classification and regulatory pathways for stem cell-based cosmetics

Country	Regulatory Approach	Stem Cell Product Category	Regulatory Body	Remarks
South Korea	Functional cosmetics with clinical evidence required	Cosmeceutical	Ministry of Food and Drug Safety (MFDS)	Allows stem cell-derived media, requires safety data
European Union	Banned ingredients list & pre-market assessment	Prohibited (human-derived SC)	European Medicines Agency (EMA)	Prohibits use of human cells/tissues in cosmetics

Table 2 (Continue) Global classification and regulatory pathways for stem cell-based cosmetics

Country	Regulatory Approach	Stem Cell Product Category	Regulatory Body	Remarks
Japan	Notification system with scientific justification	Functional cosmetics	Ministry of Health, Labour and Welfare	Encourages post-market surveillance
United States	Dual track: cosmetic or drug depending on claims	Cosmetic or OTC	FDA (Office of Cosmetics and Colors)	Cosmetic unless therapeutic claims are made
Indonesia	Notification system under ACD framework	General cosmetic (no SC classification)	BPOM	No specific rule for stem cell-derived products

Indonesia's national policy stance has been largely reactive. Regulatory authorities rely on post market surveillance rather than anticipatory assessments, such as ingredient origin tracing, toxicological profiling, or clinical claims evaluation. **Table 3** presents a matrix of the risk categories associated with stem cell-based cosmetic ingredients, highlighting areas that are currently unaddressed in Indonesian cosmetic safety assessments. This approach often leaves gaps in accountability when cosmetic products lead to adverse effects (Nuragustini et al., 2024). Furthermore, manufacturers are not obliged to disclose the specific stem cell type used whether embryonic, adult mesenchymal, or induced pluripotent, which may have ethical, legal, and safety implications (A. Y. Lestari et al., 2023). This regulatory silence on stem cell provenance diverges from the EU and U.S. frameworks, where ethical review boards and ingredient traceability are mandatory in similar contexts.

Table 3 presents a matrix of the risk categories associated with stem cell-based cosmetic ingredients, highlighting areas that are currently unaddressed in Indonesian cosmetic safety assessments.

Table 3 Potential risk matrix of stem cell-based cosmetic ingredients

Risk Category		Risk Description	Impact Level	Current Indonesian Mitigation
Biological Contamination		Potential presence of residual DNA, endotoxins, or pathogens in culture media	High	Not specifically addressed in cosmetic regulation
Misleading Claims		Unsubstantiated rejuvenation or regenerative claims	Medium	No scientific validation required pre-market
Ingredient Ambiguity	Source	Lack of transparency on whether stem cells are plant-based or human-derived	High	Not differentiated in notification system
Allergenicity		Unknown immunogenic response from bioactive factors	Medium	Labeling required but not clinically evaluated
Ethical Concerns		Use of human-derived biological material without disclosure	High	No bioethical standards mandated

The impact level presented in **Table 3** was determined through a qualitative synthesis of existing literature, expert judgment, and comparative regulatory frameworks. Each risk category such as biological contamination, misleading claims, or ethical concerns was evaluated based on two main dimensions: the potential severity of its consequences on public health or consumer trust, and the likelihood of its occurrence under current Indonesian regulatory conditions. Risks labeled as “High” are those that, if unmitigated, could result in significant harm or regulatory breaches, such as the presence of residual DNA or undisclosed use of human-derived materials. “Medium” impact refers to risks that are moderately disruptive such as allergenicity or unsubstantiated claims which may not directly endanger health but can undermine product credibility and market integrity. This stratification is consistent with internationally accepted approaches in cosmetic safety assessments, particularly those adopted by the European Union’s SCCS and Japan’s post-

market surveillance systems. The matrix serves not only to highlight current blind spots in Indonesia's oversight of stem cell cosmetics, but also to prioritize regulatory actions based on the gravity and urgency of each risk.

Table 4. Finally, studies suggest that Indonesian consumers have limited access to reliable safety information and often depend on marketing narratives or influencers to evaluate product efficacy (Ananda, 2024). This has led to the widespread circulation of unregistered products with exaggerated claims, including imported cosmetics with questionable compositions. This consumer landscape highlights the need for a responsive regulatory framework that aligns scientific oversight with market behavior (Sakti & Dinanti, 2020). Building on the above findings, Table 4 outlines policy recommendations drawn from global best practices that could guide Indonesia's strategic response to emerging cosmetic biotechnologies.

Table 4 Policy recommendations for Indonesia based on international best practices

Policy Area		Recommended Action	Benchmark Country	Rationale
Classification System		Introduce specific category for biotechnology-based cosmetics (e.g., cosmeceuticals)	South Korea	Provides clear regulatory route and safety requirements
Safety Assessment		Require pre-market toxicology and allergenicity tests for stem cell derivatives	Japan	Ensures consumer protection through scientific validation
Ingredient Transparency		Mandate origin disclosure and labeling of stem cell source	European Union	Addresses ethical and consumer rights concerns
Scientific Board	Advisory	Form an interdisciplinary advisory board for high-tech cosmetic review	United States	Brings evidence-based evaluation to regulatory decisions
Post-Market Surveillance		Establish a reporting system for adverse events involving biotech cosmetics	ASEAN Harmonization	Strengthens real-time monitoring and accountability

The findings of this review highlight that Indonesia lacks a comprehensive regulatory framework that specifically address stem cell-based cosmetic products. Indonesian regulations state that cosmetic ingredients from stem cells only originate from animals and plants, whereas human cells are prohibited (Badan POM, 2022). The use of stem cells for therapeutic purposes has been clearly regulated (Badan POM, 2025). Although stem cell derivatives are increasingly used in anti-aging and rejuvenating formulations, BPOM treats them under general cosmetic notification systems without mandatory toxicological or clinical validation. This regulatory ambiguity aligns with previous findings that underscore Indonesia's lag in aligning scientific innovation with adaptive policy instruments (Rosadi et al., 2024). The lack of specific regulatory guidelines for new cosmetic technologies is a common issue across many jurisdictions (Gupta et al., 2022).

This study confirms a broader trend identified in international policy comparisons, where regulatory frameworks in countries such as South Korea and Japan categorize stem cell-based ingredients as “functional cosmetics” or cosmeceuticals, requiring efficacy data and post-market surveillance. By contrast, Indonesia's regulatory stance is non-differentiative, creating both legal and commercial uncertainties. These findings reinforce the position argued by Marliana and Israhadi (2024), who identified a substantial legal void in the oversight of stem cell technologies, resulting in limited guidance for stakeholders and a high potential for ethical conflict (Marliana & Israhadi, 2024). Many countries struggle to keep pace with scientific innovations in cosmetics, leading to regulatory gaps and ambiguities (Goktas & Grzybowski, 2025).

These findings have several significant implications. They signal the need for BPOM to reform its approach not only to accommodate innovation but also to ensure consumer safety. The adoption of a new cosmetic classification system that includes biotechnology-based formulations can bridge this regulatory gap. Furthermore, standardizing ingredient source disclosures and integrating pre-market safety evaluations would place Indonesia's oversight closer to international best practices (Yustina et al., 2024), the use of biotechnology and fermentation in cosmetic production are necessitate updated regulatory frameworks to ensure both innovation and safety (Pérez-Rivero & López-Gómez, 2023).

The cause of Indonesia's regulatory inertia may lie in institutional fragmentation and a lack of coordinated policy discourse on cosmetic biotechnology, the regulatory approaches to cosmetics and

biotechnology vary significantly across countries (Ferreira et al., 2022). Unlike pharmaceutical regulations, which are governed by multiple expert panels, the cosmetic division of the BPOM has yet to establish a dedicated scientific advisory board for assessing stem cell-based claims. As Dewi et al. (2022) emphasized, the absence of integrated legal interpretation mechanisms hampers the state's ability to adapt regulatory frameworks to rapid technological change (Dewi et al., 2009).

In this context, this study establishes a multidisciplinary advisory framework that includes legal experts, biotechnologists, and consumer protection authorities. Such an approach would enable evidence based policymaking and foster adaptive regulation, ensuring that innovations do not outpace legal oversight. Mesenchymal stem/stromal cells (MSCs) have significant potential in regenerative medicine and cosmetics because of their self-renewal and differentiation capabilities (Zhao et al., 2021). In alignment with Dye's policy theory, the current regulatory gap in Indonesia exemplifies a form of passive policymaking, wherein governmental inaction signifies implicit choices (Bestari, 2023).

Based on these insights, the most urgent recommendation is to develop interim guidelines for stem cell cosmetic ingredients. These could include risk profiling tools, label transparency protocols, and incentives for ethical sourcing. The interim guidelines for stem cell cosmetic ingredients in Indonesia could benefit from adopting a holistic approach, including implementing risk profiling tools similar to those used in safety assessments of cosmetic products (Barthe et al., 2021). Integrating these steps into the ACD framework would not only benefit Indonesia's domestic regulations but also prepare the country for future ASEAN harmonization in biotechnology governance. The development of self-preserving personal care products using multifunctional ingredients demonstrates the industry's efforts to create safer and more natural alternatives (Senthilkumar et al., 2024).

4. Conclusion

This study revealed an unexpected yet critical finding: Indonesia currently regulates advanced biotechnology-based cosmetics, particularly stem cell derivatives, under the same category as conventional products without specialized oversight mechanisms. Despite their growing popularity and biological activity, stem cell-based cosmetics persist within a regulatory gray area where no clear protocols exist for evaluating their safety, efficacy, or source origin. The consequences of this gap include inconsistent product claims, limited consumer protection, and heightened legal and ethical risks particularly when products use sensitive or human-derived ingredients.

This study contributes to the field both theoretically and practically. This advances the application of public policy theory to cosmetic regulation by framing government inaction as a policy choice with tangible public health consequences. This offers a structured framework for how Indonesia can evolve its regulatory architecture to address biotechnology-driven cosmetics. By benchmarking international practices and proposing national policy interventions, this study serves as a guide for regulators, industry stakeholders, and legal scholars to navigate the emerging intersection between cosmetic innovation and legal oversight.

However, this is limited by its reliance on secondary data and non-systematic literature selection, inherent to the Narrative Literature Review approach. Future research could explore consumer perspectives on labeling transparency and ethical concerns through empirical studies or by investigating industry readiness for regulatory compliance. Expanding the analytical framework to include stakeholder interviews and policy simulations could also strengthen the model proposed in this study, paving the way for more inclusive and effective regulatory reforms in Indonesia's evolving cosmetic landscape.

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