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REGULATORY APPROACHES IN SELECTED COSMETICS MARKETS IN THE CONTEXT OF INSTITUTIONAL DISTANCE, INSTITUTIONAL VOIDS AND COMPLIANCE

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Purpose: The aim of this article is to analyze and compare selected regulatory systems governing cosmetics markets in the context of institutional distance, institutional gaps and compliance mechanisms and to determine how differences in regulatory frameworks shape institutional conditions in international cosmetics markets.
Design/methodology/approach: The paper is based on a literature review. The study draws on academic publications indexed in databases such as Elsevier, Springer, and ResearchGate. The analysis focuses on theoretical contributions related to institutional distance, institutional voids, and compliance, as well as on studies describing regulatory frameworks in selected cosmetics markets.
Findings: The analysis shows that regulatory systems in the examined regions differ significantly in terms of formalization and enforcement. The EU represents a highly formalized and preventive regulatory model, the USA demonstrates an evolutionary shift from self-regulation toward increased formalization, while ASEAN reflects a harmonized but unevenly enforced regulatory framework. These differences are reflected in varying levels of institutional distance and the presence of institutional voids, particularly in relation to regulatory consistency and enforcement mechanisms.
Research limitations/implications: The study is based on a literature review and does not include primary empirical data. Future research could extend the analysis by incorporating empirical case studies of firms operating across different regulatory environments.
Practical implications: The findings may support cosmetics companies operating internationally in understanding differences in regulatory environments across key markets. The study highlights the importance of compliance mechanisms in managing regulatory risk and adapting organizational processes to varying institutional conditions. This may contribute to more effective compliance strategies.
Originality/value: This paper provides a structured interpretation of regulatory diversity across three major global regions and contributes to international business and regulatory studies by linking institutional theory with compliance practices in the context of cosmetics companies operating in international markets.
Keywords: cosmetics market, institutional distance, institutional voids, compliance.
Category of the paper: research paper.

1. Introduction

The international expansion of cosmetics companies is increasingly shaped by the complexity of foreign market regulations. Differences in the legal frameworks governing product safety, market authorizations, and compliance obligations create a heterogeneous institutional environment that significantly impacts companies operating across borders. As a result, cosmetics companies entering foreign markets must not only adapt to consumer preferences and competitive conditions but also to varying regulatory and compliance requirements.

In this context, the European Union (EU) is one of the most regulated cosmetics markets in the world. The EU system is characterized by a preventive approach to product safety, extensive documentation requirements and a high degree of institutional formalization. While this ensures a high level of consumer protection and regulatory predictability, it also creates significant barriers to market entry, particularly for non-EU companies, which often operate under less stringent regulations. For example, companies from Asian and North American markets often face significant difficulties in adapting upon entering the EU market due to differences in regulatory structure, responsibility allocation and enforcement mechanisms. These differences illustrate the importance of the concepts of institutional distance and institutional gaps, which help explain the complexities of operating in different regulatory environments.

The aim of this article is to analyze and compare selected regulatory systems governing cosmetics markets in the context of institutional distance, institutional gaps and compliance mechanisms. The study is based on a literature review conducted using academic databases such as Elsevier, Springer, and ResearchGate. The analysis includes academic publications on institutional distance, institutional gaps and compliance, as well as studies on the regulatory frameworks in selected cosmetics markets. On this basis, the following research questions are addressed:

- What regulatory approaches operate in the selected cosmetic markets?
- How does the degree of formalization of regulatory systems relate to the predictability of the legal environment and the compliance costs borne by cosmetics companies?

2. Theoretical foundations of institutional distance and institutional voids

Distance constitutes a fundamental concept in the theory of institutional trade and international business (Ciszewska-Mlinarič, Wąsowska, 2012, p. 5). Although it is commonly associated with physical or geographical separation, in the context of international management the concept has a much broader meaning. S. Beugelsdijk, B. Ambos and P.C. Nell noticed that distance should be understood as a construct whose significance depends on the theoretical perspective within which it is analysed (Beugelsdijk, Ambos, Nell, 2018). Consequently, within transaction cost theory, distance may be interpreted as a source of additional costs whereas in agency theory it may constitute a cause of control and monitoring problems. From the perspective of international management distance should therefore not be viewed merely as a measure of differences but rather as a factor influencing specific organizational decision-making mechanisms.

The multidimensional nature of the concept of distance is emphasized in numerous typologies developed within the international business literature. One of the most influential approaches is P. Ghemawat's CAGE framework (Ghemawat, 2001). This acronym refers to four dimensions of distance that firms must take into account when entering or operating in foreign markets: cultural, administrative, geographical and economic distance. The framework provides a structured analytical tool enabling the identification of the costs associated with conducting business abroad as well as the recognition of institutional gaps (Judijanto, 2025, p. 143). Moreover, the CAGE framework has been applied in the analysis of both developed and emerging economies with particular emphasis on the internationalization processes of firms originating from emerging markets (Ye, Don, Alam, 2023).

From the perspective of this study institutional distance is of particular importance. In broad terms, it is defined as the difference between the institutional profiles of two countries, typically the home country and the host country of a multinational enterprise (Kostova, 1996). The concept may also be understood as a measure of the compatibility of the quality of institutions operating within both countries (Long et al., 2023). T. Kostova et al. indicate that, within the scientific literature, institutional distance may be analysed from the perspective of three theoretical approaches: organizational institutionalism, institutional economics and comparative institutionalism which are discussed in Table 1.

Table 1.
Institutional distance in different theoretical perspectives

Comparative feature	Organizational institutionalism	Institutional economics	Comparative institutionalism
Disciplinary roots	Sociology	Economics	Political economy and political sociology
Definition	Refers to Scott's three institutional pillars. Institutional distance between countries consists of differences in the regulative, cognitive and normative dimensions	Refers to differences in the quality of institutional environments and the extent to which they support efficient economic coordination. Two types of institutional distance are distinguished: formal (relating to laws and rules) and informal (relating to values, norms and beliefs)	Institutional distance is understood as the difference between institutional configurations of individual countries or between institutional clusters that shape the functioning of economies and organizations. In this approach distance does not refer only to individual parameters but to the overall character of a country, including independencies between legal, market, social and political structures
Mechanism of action	Legitimacy: companies must adapt to local requirements and social expectations in order to gain acceptance	Transaction costs: emphasis is placed on reducing uncertainty and risk. Institutional distance increases transaction costs arising from inefficiencies or limited effectiveness of market mechanisms	Fit: companies align their resources with the institutional configurations of the host country

Source: (Kostova et al., 2020).

Referring to the CAGE framework, institutional distance may be interpreted through a formal and informal lens, consistent with the assumptions of institutional economics. In the former case, it is therefore associated with administrative and economic distance. In contrast, from an informal perspective, cultural distance becomes particularly relevant (Ye, Don, Alam, 2023) which in the literature is most frequently analysed with reference to Hofstede's cultural dimensions as well as data from the *Global Competitiveness Report of the World Economic Forum* (Silva, Ogasavara, Pereira, 2023). Theoretical studies on institutional distance often highlight a key relationship, namely that the higher the institutional distance, the more difficult it is to transfer business practices and routines from headquarters to foreign subsidiaries. This is confirmed by the study conducted by X. Lu, S.J.M. Boo and X. Liu. According to them, despite suggestions regarding a potentially positive impact of institutional distance on subsidiary performance, the prevailing view in the literature is that greater institutional distance reduces the efficiency of multinational enterprise subsidiaries due to the additional costs of conducting business abroad arising from institutional differences (Lu, Boo, Liu, 2024).

In the context of institutional distance, institutional voids are also frequently discussed. They refer to the absence or insufficient development of key formal institutions, such as political, financial or regulatory structures which are essential for the efficient functioning of markets (Palepu, Khanna, 1998). According to J. Barbar, however, this definition is not sufficient. In contemporary terms, institutional voids should be understood more broadly as conditions that restrict market access and hinder its functioning, thereby directly affecting firms' activities (Barbar, 2025, pp. 69-70). According to U. Stephan, L.M. Uhlaner and C. Stride (2025), institutional voids can be classified according to the type of institution involved in Table 2. Similarly to high institutional distance, institutional voids are also treated in international management research as constraints that require organizations to develop new adaptive responses (Doh et al., 2017). With reference to the cosmetics industry context, institutional voids may manifest themselves in the form of insufficient cosmetic safety standards, a lack of adequate supervisory mechanisms, underdeveloped certification or accreditation systems or incomplete consumer protection regulations.

Table 2.
Institutional voids according to the type of institution

Type of void	Description
Constitutional void	Occurs when a country lacks the rule of law or an effective property rights protection system. Under such conditions, transaction costs increase and certain social groups may be excluded from the market
Governmental void	Occurs when the role of the state in providing citizens with basic social needs is limited or entirely absent. As a consequence, overall economic productivity may be weakened
Normative void	Occurs when there is a lack of cultural and social norms that facilitate cooperation
Cognitive void	Arises from cultural differences and variations in market participation patterns. However, it does not block economic activities; instead, it shapes the way it is conducted

Source: (Stephan, Uhlander, Stride, 2025).

3. The role of compliance

Compliance is an interdisciplinary concept that relates not only to law, management and economics but also to psychology, philosophy and medicine. However, in relation to the subject matter of this article, the discussion presented herein will primarily refer to the first three disciplines. According to the adopted research perspective, compliance is understood as adherence to rules and conformity with established norms (Kovalchuk, Morenchenko, Bibik, 2023, p. 18). It encompasses all measures and methods aimed at ensuring compliance with rules of conduct, including those extending beyond statutory law, such as ethical principles and

best practices (Janik, 2020, p. 26). The literature frequently highlights the strategic dimension of compliance. It strengthens organizational structures by eliminating irregularities that may result in legal sanctions or reputational damage while in the long term enhancing organizational culture and increasing a firm's competitiveness (Szpringer, 2016, p. 94). A similar view is presented by J. Olszewski, who argues that properly implemented compliance, also understood as an institutional determinant, leads to multiple benefits, including more effective management processes, enhanced organizational credibility and increased transparency and security (Olszewski, 2022, p. 671).

The origins of compliance are commonly associated with business practices in the United States. M.W. Kuliński notes that the development of this concept began with the adoption of the first federal laws regulating the American market (Kuliński, 2020, p. 125). A major turning point occurred in 1977, when compliance mechanisms were formally regulated through the adoption of the Foreign Corrupt Practises Act (Barcik, 2016, p. 11). Today, researchers emphasize the evolutionary nature of compliance and firms' strategies for regulatory adherence. In the context of multinational enterprises, such practices include centralized compliance frameworks, comprehensive compliance programs, continuous monitoring and auditing, proactive risk management and litigation avoidance. Detailed information regarding the individual compliance strategies is presented in Table 3.

Table 3.
Compliance strategies

Strategy	Key activities	Objectives
Centralized compliance frameworks	- integration of global standards with local regulations, - coordination of activities between headquarters and host-country teams.	To ensure the harmonization of organizational practices while simultaneously accounting for differing legal requirements across countries
Comprehensive compliance programs	- development of clear rules and policies, - regular employee training, - establishment of reporting procedures for violations.	To foster an ethical and responsible organizational culture while ensuring that all employees are aware of their obligations
Continuous monitoring and auditing	- regular review of risk indicators, - independent internal audits, - assessment of the effectiveness of procedures.	To enable early detection of gaps in the system, increase transparency and facilitate the rapid implementation of corrective actions
Proactive risk management	- identification of threats (risk registers, checklists), - qualitative and/or quantitative analyses, - scenario planning.	To prevent the escalation of legal issues, ensure business continuity and mitigate the impact of unforeseen events
Litigation avoidance	- use of ADR clauses (arbitration, mediation), - stakeholder dialogue, - ongoing legal advisory support.	To reduce litigation costs, accelerate conflict resolution and maintain a stable business environment

Source: (Latilo et al., 2024).

The compliance strategies presented in Table 3 acquire particular significance in the context of cosmetics companies due to the extensive regulatory obligations concerning product safety and consumer protection. Unlike many other industries, cosmetics manufacturers must ensure continuous compliance not only during product development but also throughout the entire product life cycle. Consequently, centralized compliance frameworks facilitate the coordination of product notifications, technical documentation and regulatory requirements across different jurisdictions, while allowing firms to adapt to country-specific legal provisions regarding cosmetic ingredients and labeling. Comprehensive compliance programs support the preparation and maintenance of Product Information Files (PIFs), Cosmetic Product Safety Reports (CPSRs) and other regulatory documentation required before products are placed on the market. At the operational level, continuous monitoring and auditing include regular verification of Good Manufacturing Practice (GMP) compliance, supplier qualification, product documentation and post-market surveillance, including the reporting of serious undesirable effects where required by law. Proactive risk management further enables cosmetics firms to monitor emerging toxicological evidence, assess the safety of cosmetic ingredients and implement product reformulations following regulatory amendments or new scientific findings. Litigation avoidance strategies complement these activities through comprehensive documentation, effective corrective actions and continuous demonstration of regulatory compliance, thereby reducing legal and reputational risks. Collectively, these compliance strategies help multinational cosmetics companies manage regulatory diversity across international markets, mitigate institutional voids and reduce the challenges associated with institutional distance.

4. Regulatory approaches of selected cosmetics markets in the context of institutional distance and compliance activities

For cosmetics companies operating internationally, one of the major challenges involves functioning within diverse regulatory systems existing across different regions of the world. These differences concern not only the degree of regulatory formalization or the scope of institutional supervision but also approaches to product safety responsibility and mechanisms of legal enforcement. Consequently, they directly affect the conditions for conducting business activities in foreign markets, the level of market entry barriers and the scope of adaptation measures undertaken by cosmetic companies. These regulatory differences are closely related to the occurrence of institutional distance and institutional voids which determine the scope of implemented compliance mechanisms.

Accordingly, this article analyses three regulatory systems: public regulation characteristic of the EU countries, the self-regulatory model associated with the US and the regulatory harmonization approach applied, among others in Malaysia. The selection of these examples is deliberate and results from the need to present distinct approaches to cosmetic market regulation functioning across global markets. The analysed systems represent varying levels of regulatory formalization, the scope of responsibility imposed on business entities and the role of supervisory institutions, thereby enabling a comparison of different institutional conditions and the related compliance requirements.

To enable a systematic comparison of the analysed regulatory systems, the concepts of institutional distance and institutional voids are operationalized using selected regulatory criteria. Institutional distance is assessed through differences in the degree of regulatory formalization, the scope of compliance obligations imposed on manufacturers, the role and powers of supervisory authorities and the consistency of regulatory enforcement. Greater divergence across these dimensions indicates a higher level of institutional distance between regulatory systems. Institutional voids are examined with reference to the availability and effectiveness of formal regulatory mechanisms supporting market governance. Particular attention is paid to the existence of mandatory product notification systems, documentation requirements, Good Manufacturing Practice (GMP) obligations, product safety assessment procedures, post-market surveillance and adverse event reporting, as well as the consistency of regulatory enforcement. Institutional voids are considered more pronounced where these mechanisms are absent, incomplete or unevenly enforced, thereby increasing uncertainty for firms operating in international markets. These criteria provide a common analytical framework for comparing the regulatory approaches adopted in the EU, the United States and ASEAN, while simultaneously explaining differences in compliance requirements imposed on cosmetics manufacturers.

In the EU, as mentioned, the dominant model is public regulation characterized by a high level of formalization and compliance mechanisms (Gautam et al., 2022). This system is based on the requirement to demonstrate product safety prior to market entry, which is reflected in extensive documentation and control obligations. Key elements include, among others, the obligation to apply Good Manufacturing Practice (GMP) standards, notify products through the Cosmetic Products Notification Portal (CPNP), prepare a Cosmetic Product Safety Report (CPSR), and maintain a Product Information File (PIF). The latter two are not one-off activities. They must be updated on an ongoing basis, especially in the event of a formulation change or the emergence of new information about the product, such as the detection of banned substances (Ferreira et al., 2022). The high level of regulatory formalization in the EU limits the occurrence of institutional voids and implies a high degree of predictability in the regulatory environment. However, it simultaneously generates significant compliance costs for companies. From the perspective of international firms, particularly those originating from countries with less stringent regulatory frameworks, compliance with EU requirements may

necessitate substantial organizational and procedural adjustments. Consequently, the EU model places considerable emphasis on proactive compliance measures, including continuous documentation management, regulatory monitoring, and systematic risk assessment throughout the product lifecycle.

A different system is represented by the US where for a long time the dominant model was based on self-regulation and limited state intervention in the cosmetic market. Until recently, the regulatory framework was primarily based on the Federal Food, Drug, and Cosmetic Act (1938) and the Fair Packaging and Labeling Act (1966) which established a limited scope of mandatory regulatory requirements for cosmetic products. Prior to the entry into force of the Modernization of Cosmetics Regulation Act (MoCRA) in 2022, the system was characterized by a relatively low level of formalization and a limited scope of regulatory obligations imposed on companies. An important role was played by the Voluntary Cosmetic Registration Program which was voluntary in nature and did not constitute a mandatory market control instrument. As a result, regulatory oversight by the U.S. Food and Drug Administration (FDA) was limited, and many compliance-related activities remained voluntary in nature. Cosmetic companies were not required to comply with GMP or report adverse events to the FDA (Patel et al., 2025). From an institutional perspective, this regulatory configuration generated significant institutional voids, particularly in the areas of product safety monitoring, standardized compliance requirements and post-market surveillance mechanisms.

The introduction of MoCRA represented a major shift towards greater system formalization and a strengthened role of the Food and Drug Administration, including requirements such as facility registration, adverse event reporting, and GMP compliance (FDA, 2022). In addition, MoCRA significantly expanded the enforcement powers of the FDA, including the ability to request product recalls in cases of misbranding or safety concerns. These changes contributed to a partial reduction of institutional voids by establishing more structured mechanisms of market oversight and product safety control. Nevertheless, several regulatory gaps remain. In particular, the classification of cosmetic products may overlap with drug regulation depending on their intended use (Rebbaniboni et al., 2024), while the US system still lacks a comprehensive database of permitted cosmetic ingredients and standardized testing methods for detecting asbestos contamination in talc-containing products (Stoiber, Fitzgerald, Leiba, 2020).

The third model under consideration is harmonization. This model represents an intermediate solution between the European and American systems. While it incorporates a number of formal regulatory requirements similar to those found in the European Union, it is simultaneously based on regional coordination mechanisms intended to ensure regulatory consistency across multiple regions. Harmonization is characteristic of the Association of South-East Asian Nations (ASEAN), including Malaysia, where the cosmetics market is supervised by the Ministry of Health through the National Pharmaceutical Regulatory Agency (NPRA). A major regulatory milestone was the implementation of the ASEAN Cosmetic

Directive and the introduction of a notification system in 2008, aimed at aligning national regulations with regional standards applied across ASEAN member states (Othman et al., 2024). The harmonization model incorporates a range of compliance requirements, including product notification, maintenance of product documentation, adherence to GMP standards, adverse event reporting, and product safety assessments based on ingredients, chemical structure, and exposure levels. In this respect, the ASEAN framework shares several characteristics with the European regulatory approach. At the same time, however, it remains less formalized than the EU system and allows for greater variation in implementation and enforcement across member states. Importantly, despite the existence of harmonized regulatory standards, cases of non-compliance among cosmetic manufacturers continue to be reported in practice. This suggests that institutional voids remain present and that regulatory harmonization does not automatically guarantee uniform enforcement or full compliance with legal requirements (Othman et al., 2024).

5. Summary

The functioning of cosmetic companies in an international context is strongly determined by the diversity of regulatory systems operating in different regions of the world. These differences concern not only the degree of regulatory formalization, but also the scope of corporate responsibility as well as the mechanisms of supervision and law enforcement, which directly translates into the level of institutional distance and the occurrence of institutional voids. The comparative analysis demonstrates that these two concepts provide a useful analytical framework for explaining how regulatory heterogeneity shapes the operating conditions of multinational cosmetic companies.

In this context, particular importance should be attached to the comparison of three regulatory models: the EU system of public regulation, the US model evolving from self-regulation towards greater formalization, and the regulatory harmonization system applied within ASEAN. Each of these models generates different operating conditions for cosmetic companies, varying both in terms of the predictability of the regulatory environment and the scope of compliance requirements. The findings indicate that a high level of regulatory formalization reduces the risk of ambiguity and institutional voids, while simultaneously increasing adaptation costs for companies. In contrast, systems with a lower degree of formalization provide greater operational flexibility, but are associated with higher regulatory uncertainty and the need for a more adaptive approach to compliance requirements. These results confirm that institutional distance is primarily driven by differences in regulatory formalization, enforcement intensity and supervisory capacity across jurisdictions.

Consequently, compliance should be understood not only as a tool for ensuring adherence to legal regulations, but also as an essential element of corporate functioning within diverse institutional environments. It encompasses activities related to regulatory risk management, monitoring of legal changes, maintenance of documentation, and ongoing adjustment of organizational procedures, thereby constituting a key component of operating under conditions of institutional distance. At the same time, the analysis shows that compliance mechanisms serve as a practical response to institutional voids by reducing uncertainty, improving regulatory predictability and facilitating international market entry for cosmetics companies.

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