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A COMPARATIVE CASE STUDY ON COSMECEUTICAL REGULATORY FRAMEWORKS IN INDIA , USA AND SOUTH KOREA

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Abstract:
The cosmetics sector is the most rapidly growing segment of the beauty business. Herbs employed for their therapeutic properties to address various systemic ailments are also utilized to enhance one's appearance. Numerous commercially available cosmetics claim to have skin-enhancing characteristics, such as anti-aging benefits, when applied topically. Due to the plethora of these materials and the extensive variety of skin appearance impacts they encompass, this brief contribution must therefore be selective regarding the number of materials discussed and the thoroughness with which each single substance is examined. The advent of BB cream, or blemish balm/beauty balm, in 2011 marked the arrival of Korean beauty in the West. This skincare product was marketed as a multifunctional item suitable for use as a foundation, moisturizer, and sunscreen. Since that time, Korean cosmetics have gained significant popularity among consumers globally and remain firmly established in the United States, the nation's third-largest export market. This comparative analysis examines the regulatory frameworks for cosmeceuticals in South Korea, the United States, and India, emphasizing the assurance of safety, efficacy, and stability, while highlighting discrepancies and challenges in policy modification and harmonization.

Keywords: *Thematic synthesis, regulatory harmonization, global frameworks, consumer safety, policy convergence, regulatory challenges, public health policy.*

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INTRODUCTION:

Products that combine the fields of cosmetics and pharmaceuticals and are referred to as "cosmeceuticals" are intended to improve a person's health and look by bringing about a certain effect. The term "cosmeceutical" comes from the Drugs and Cosmetics Act of 1940, which states that it can refer to both cosmetics and pharmaceuticals. The Act defines "drugs" as "any article intended to be rubbed, poured, sprinkled, or sprayed on or introduced into or applied to any part of the human body for cleaning, beautifying, promoting attractiveness, or altering the appearance and includes any article intended for use as a component of cosmetics" and "any medicines for internal or external use of humans or animals and all substances intended to be used for; or in the diagnosis, treatment, mitigation, or prevention of any disease or disorder in humans or animals" [1]. Cosmetics are also included in the definition of "drugs." India's market for cosmeceutical products is growing at a faster rate than in other countries. Two of the most important factors that will contribute to the future growth of the Indian market are the expansion of the retail sector and the presence of enormous manufacturing potential. There has been a substantial shift in consumer attitudes regarding cosmeceutical products, which has resulted in the cosmetics industry in India going through significant changes in recent years. There has been a shift in the socioeconomic position of Indian consumers, notably women, which has led to an expansion of the business [2]. In a gathering that took place approximately twenty years ago, Albert Kligman came up with the term "cosmeceutical." Biologically active substances that possess pharmacological or therapeutic activities are stated to be present in this category of cosmetic product. In addition, they fulfill the requirements of health and beauty. It is possible to make use of a wide variety of materials as functional ingredients, regardless of whether they are developed through chemical processes or sourced from plants or animals. A great number of cosmetic items that contain biologically active substances have been developed and introduced in recent years, despite the fact that there are variations in the regulations and approvals that are imposed by the government. When it comes to cosmeceuticals, the inquiry and synthesis of composite active compounds should be based on their disclosed origins, structures, and methods of skin interaction. Most importantly, the safety and effectiveness of these compounds on certain skin components should be taken into consideration. In this article, we take a look at a few cosmeceuticals that represent different categories of functions, paying special emphasis to the components of these cosmeceuticals that are physiologically active [3]. The objective is to present a comprehensive analysis of the regulatory frameworks that govern cosmeceuticals in South Korea, the United States of America, and India. The purpose of this study is to investigate the evolution of cosmeceutical policies in these nations and to identify the difficulties associated with matching regulations. to investigate the possibility of harmonizing the regulatory methods used by these countries and to compare and contrast them.The scope of this review article is to examine the regulatory frameworks that govern the use of cosmeceuticals in India, the United States of America, and South Korea to include the following: This article provides an analysis of the rules, regulations, and guidelines that govern the use of cosmeceuticals worldwide.Policy evolution is an investigation into the ways in which cosmeceutical policies have evolved over the course of time in each nation. The challenges of harmonisation includes a discussion of the problems that arise when trying to match regulations across all three countries. A comparison of the regulatory approaches used by India, the United States of America, and South Korea, with an emphasis on the similarities and differences between the three countries. There are opportunities for harmonization, which include the investigation of possible opportunities to harmonize legislation in order to facilitate the worldwide development and commercialization of cosmeceuticals [3].

Comparative Cosmeceutical Regulatory Frameworks: India, USA, South Korea

RESEARCH METHODOLOGY:

❖ Study Design

This research employs a comparative case study methodology that is based on qualitative information analysis. An in-depth research of complex regulatory systems in real-world situations is made possible through the utilization of a case study methodology technique. For the purpose of this comparison, three national regulatory environments were selected: India, the United States of America, and South Korea. These countries were selected due to their substantial cosmeceutical markets and distinctive regulatory philosophies. The qualitative design of the study lays a significant emphasis on the interpretation of normative and policy documents, such as laws, guidelines, and official publications, with the goal of determining the fundamental regulatory principles, methods of implementation, and requirements for compliance. Instead of focusing on numerical measurement or statistical hypothesis testing, this technique, in contrast to quantitative research, is more concerned with understanding regulatory frameworks, similarities and variations, and concerns regarding harmonization across countries.[4]:

Table: Regulatory Aspects of Cosmeceuticals in India, USA, and South Korea

Regulatory Aspect	India	USA	South Korea
Regulatory Authority	CDSCO, BIS, AYUSH, FSSAI	FDA, FTC, CIR	MFDS (formerly KFDA)
Legal Status of Cosmeceuticals	No specific legal definition	No specific legal definition	Recognized as "Functional Cosmetics"
Pre-Marketing Approval	Not required for cosmetics	Required only for OTC drugs and color additives	Mandatory for functional cosmetics
Product Categories	Cosmetics, Drugs, Herbal products, Nutraceuticals	Cosmetics, OTC Drugs	Cosmetics, Functional cosmetics, Quasi-drugs
Claims Regulation	Moderate; governed by BIS standards	Strict; regulated by FDA and FTC	Strict evaluation for functional claims
Safety Testing	Basic tests (microbial, stability)	Not mandatory for cosmetics (except OTC); safety must be ensured	Mandatory safety and efficacy testing
Labelling Requirements	Ingredient list, MRP, batch number, warnings	Full INCI list, warnings, Drug Facts (if OTC)	Full INCI list, functional claims, mandatory warnings
Post-Marketing Surveillance	Developing; CDSCO monitors adverse drug reactions (ADRs)	Strict under MoCRA regulations	Strong surveillance and recall system

Data Sources
All of the material that is evaluated is based on official records and publications that have been reviewed by other researchers. This is because the study solely employs secondary data sources. In order to gather information, we examined the following sources in a consistent manner.Official regulatory authorities' websites are available here.On these websites, you will find the regulatory regulations, guidelines, and legal requirements that belong to cosmeceutical products that are the most dependable and up to date.

Central Drugs Standard Control Organization (CDSCO) of India is the source of India's Drugs and Cosmetics Act, 1940, as well as the rules that accompany it. These rules include cosmetic legislation and administrative recommendations that are related to them.

The Food and Drug Administration (FDA) of the United States is responsible for providing regulations that pertain to cosmetics and other things that are related to them. These regulations include enforcement guidelines, guidelines for labeling and claims, and classification criteria.

The Ministry of Food and Drug Safety (MFDS) of South Korea is responsible for enforcing the laws and rules that pertain to cosmetics and quasi-drug products in South Korea. These laws and guidelines embody market controls and consumer safety requirements.[4]:
Guidelines for regulatory compliance and previously published studies

For the purpose of gaining an understanding of scholarly interpretations of cosmetic and cosmeceutical regulation, documents that were subjected to peer review were examined. These interpretations included comparative viewpoints, theoretical frameworks, and confirmed regulatory issues.

Identification of Similarities and Differences
In the last stage of the analysis, thematic synthesis was utilized in order to systematically discover relevant trends and insights across a variety of regulatory regimes. With the help of this technique, major gaps in regulatory harmonization were able to be identified, particularly in areas where national guidelines and policies exhibit a significant amount of heterogeneity. At the same time, it assisted in bringing to light areas of convergence, such as the shared regulatory standards that place an emphasis on the safety of consumers, the quality of products, and their effectiveness.

In addition, the synthesis made it easier to have a more in-depth comprehension of the regulatory, legal, and practical obstacles that are related with the process of obtaining international harmonization. The significance of these problems was viewed in the light of broader factors that have an impact, such as continuing global policy initiatives, the level of industrial readiness, country-specific public health agendas, and the requirement to preserve regulatory sovereignty. A detailed review of this kind offers extremely helpful insights into the complexity involved in coordinating regulatory systems across a variety of jurisdictions. [5]

HARMONIZATION CHALLENGES AND POLICY GAPS

Classification Ambiguities
Legally speaking, the term "cosmeceutical" does not have a definition in a number of different jurisdictions. The Food and Drug Administration (FDA) in the United States, for example, does not accept the term "cosmeceutical" as a unique category. Instead, the FDA requires that products be classed as either cosmetics or pharmaceuticals depending on the components they contain and the claims they make.The Drugs and Cosmetics Act of 1940 provides definitions for the terms "drug" and "cosmetic," but it does not include the term "cosmeceutical," as stated in the review titled "Cosmeceuticals: a transit state." In accordance with the Korean Cosmetic Products Act (KCPA), a brand-new category that is now commonly referred to as "cosmeceuticals" was established in South Korea on July 1, 2000. On the other hand, the regulations "do not clearly establish criteria to determine when a cosmetic product becomes a cosmeceutical" or standards to evaluate the effectiveness of cosmetics.

Efficacy and Safety Testing Gaps
Standards for pre-market testing and post-market supervision of products that straddle the medical and cosmetic categories differ based on classification.The term "cosmeceutical" lacks official recognition, resulting in numerous products marketed as such in the USA not requiring FDA approval if categorized as cosmetics, according to the "Comprehensive Review on Cosmeceuticals." The criteria for demonstration of effectiveness are insufficient.[6] There is an absence of uniform directives regarding functional and efficacy testing for therapeutic assertions; however, in India, the regulatory classification of "cosmeceuticals" necessitates compliance with safety and labeling standards, including limits on heavy metals and skin irritation assessments, despite their classification as cosmetics.[7] In Korea, functional cosmetics are regulated more rigorously, with the Ministry of Food and Drug Safety (MFDS) supervising the whitening and anti-wrinkle categories; nevertheless,

the prior cosmeceutical category under the KCPA lacked clarity regarding the required evidence for efficacy.[8]

Claim Regulation and Consumer Transparency
Classification and testing discrepancies affect claim regulation. For example, what a product can say, how evidence must support it, and how clear the labeling should be all differ. The article "Cosmetic-Cosmeceutical Products: Navigating the Regulatory Gray Zone" says that the U.S. FDA does not recognize the term "cosmeceutical." This means that a product that makes therapeutic claims may be treated as a drug. For cosmetics, the label must be true and not misleading. Surveys done in India show that "the lack of guidelines on how to interpret product claims and an illustrative list of cosmetics causes differences in interpretation between licensing authorities" in different states.Companies in Korea have to deal with both functional cosmetic regulation and possible drug-classification limits. Functional cosmetics include clear legal claims, including "brightening" and "anti-wrinkle." However, the larger group of cosmeceuticals still has some gray areas when it comes to legal claims. Due to regulatory deficiencies, customers can believe that "cosmeceutical" implies drug-like regulation or strictness; however, this may not be accurate in numerous jurisdictions.[6]

Cross-border Trade and Compliance Barriers
Different countries have different rules for classification, testing, and claims, which makes it hard to sell cosmeceuticals and functional cosmetics across borders.According to the article "Cosmeceutical Formulation & Regulatory Insights in India," Chapter III of the Drugs & Cosmetics Act says that India may seek drug licenses for goods that include active ingredients or make claims of therapeutic benefits.[7] The U.S. Trade Representative's NTE report on the Republic of Korea says that "The KCPA laws about cosmeceuticals... do not make requirements clear... Efficacy must be shown by meeting a standard." People who approve things must verify to see if they work and are safe. The FDA controls the import of cosmetics into the US. However, if the items are meant to be used as medicine or make drug-like claims, they may fall under drug/OTC regulation, which makes it harder to follow the rules.

Intellectual Property and Innovation Roadblocks
The cosmeceutical business faces problems with innovation because of unclear rules and different IP/enforcement systems.

The study "Innovating Beauty: Unveiling the Role of Patents in the Cosmetic Industry" illustrates how the cosmetic and cosmeceutical industry's elevated entry barriers and competitive innovation landscape are manifested in the concentration of patent filings among major corporations.[9]

ROLE OF INTERNATIONAL REGULATORY BODIES
World Health Organization (WHO)
The WHO mostly focuses on medicines, vaccines, diagnostics, and blood products, but it also produces guidelines and standards that can affect the rules for cosmetics and other products that are partly "cosmeceutical." For example, its "Good Regulatory Practices" guideline lists nine basic rules for regulatory systems, such as legality, consistency, impartiality, proportionality, clarity, efficiency, and transparency. The World Health Organization does not set a specific worldwide standard for cosmetics or cosmeceuticals, but its work on the classification, reliance, and regulation of health commodities can aid with hybrid products.[10]

International Organization for Standardization (ISO)
Although they are not legally binding, the international technical standards created by ISO give authorities and industry a single point of reference. In the field of cosmetics. Harmonized guidelines for good manufacturing procedures, packaging, labelling, and testing across jurisdictions are provided by ISO 22715 (Packaging & Labelling for Cosmetics) and other standards.

Even in cases where regulatory classification is still inconsistent, these ISO standards aid in bridging technical harmonisation gaps (such as method validation, labelling, and packaging).Even though the regulatory (legal) classification of cosmeceuticals continues to differ, ISO standards promote the "technical" aspect of harmonisation (testing procedures, labelling consistency).[11]

Association of Southeast Asian Nations (ASEAN) Cosmetic Harmonisation
For cosmeceutical-type products and cross-border trade, ASEAN has served as a model for regional cosmetics regulatory harmonization. Important characteristics In order to standardize cosmetic product registration, mutual recognition, and technical standards among ASEAN Member States, the ASEAN Harmonized Cosmetic Regulatory Scheme (AHCRS) was signed on September 2, 2003.[13]
International Cooperation on Cosmetics Regulation (ICCR)
ICCR, a voluntary network of major regulators (Brazil, Canada, EU, Israel, Japan, Republic of Korea, and US) established to promote convergence of cosmetic regulatory procedures, is noteworthy even if it was not on your initial list. Working groups on ingredient safety evaluation,

non-animal testing techniques, and sharing best practices .A forum for regulators to agree on proof standards and talk about concerns related to borderline classification .This forum is an example of a new worldwide regulatory cooperation structure that is pertinent to the regulation of cosmetics.[14]

Emerging Frameworks for Cosmetic-Drug Hybrid Regulation
The growth of so-called "cosmeceuticals" or "functional cosmetics" has sparked discussion about hybrid regulatory approaches, even though the majority of jurisdictions treat items as either "cosmetics" or "drugs." Important points:

Some countries (like South Korea) have already started using a hybrid tier-approach by classifying "functional cosmetics" (such anti-wrinkle and whitening products) differently from regular cosmetics.

Technically, if not yet legally, bridging the cosmetic-drug gap is supported by the drive for standardized analytical methods (via ISO) and standardized testing guidelines (through WHO/ISO).

For cosmetics, the ASEAN scheme (AHCRS) switches from pre-market clearance to mostly post-market surveillance, which is more indicative of a "lighter" regulatory regime and creates the possibility of hybrid regulation.[15,16]

RESULTS AND DISCUSSION:

The comparative analysis of cosmeceutical regulatory frameworks in India, the USA, and South Korea reveals significant variations in classification, approval processes, safety evaluation, and claim regulation.
Regulatory Classification
None of the three countries (India and USA) legally recognize “cosmeceuticals” as a distinct category.
South Korea stands out by formally recognizing them as “functional cosmetics.”
This lack of uniform classification creates confusion for manufacturers and regulators.
Pre-Market Approval Differences
India: No pre-market approval for cosmetics.
USA: Required only for OTC drugs and specific ingredients. South Korea: Mandatory approval for functional cosmetics.
This shows South Korea has the most structured and strict regulatory system.
Safety Evaluation
India follows basic safety testing (microbial and stability tests).
USA places responsibility on manufacturers, with limited mandatory testing. South Korea requires rigorous safety and efficacy testing.
This indicates stronger consumer protection in South Korea.
Claims and Labelling Regulation
USA has strict claim regulation (FDA + FTC monitoring). India has moderate control with BIS standards.
South Korea enforces strict validation of functional claims.
Misleading claims remain a major concern, especially in less regulated environments.
Post-Marketing Surveillance
USA has strong post-market surveillance (MoCRA-based reporting). South Korea also has a robust recall system.
India is still developing surveillance mechanisms.
Key Challenges Identified Lack of global harmonization Ambiguity in classification
Inconsistent safety and efficacy requirements
Misleading product claims
Barriers to international trade
Overall Interpretation
South Korea provides a model regulatory framework with structured approval and safety validation.
The USA emphasizes strict claim regulation but less pre-market control.
India shows regulatory gaps and evolving systems, requiring improvement.

CONCLUSION:

The study concludes that the cosmeceutical sector operates in a regulatory gray zone, leading to South Korea’s model demonstrates how a defined regulatory category can improve safety and compliance.

India needs stronger regulations, clearer classification, and better surveillance systems. The USA requires more structured pre-market evaluation for such hybrid products.

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