

EVALUATING COMMUNICATION EFFECTIVENESS IN POST-MARKET SURVEILLANCE OF SOUTH KOREA'S COSMETICS INDUSTRY

Donthamalla Gunasheela¹, Meghana GS^{2*}

¹Department of Regulatory Affairs, Centre of Excellence in Regulatory Sciences, JSS College of Pharmacy, JSS Academy of Higher Education and Research, Mysuru, Karnataka, India-570015. Email Id: gunasheeladonthamalla@gmail.com | Phone: +91 9640351754, ORCID ID :0009-0006-5566-3321

^{2*}Department of Pharmaceutics, Centre of Excellence in Regulatory Sciences, JSS College of Pharmacy, JSS Academy of Higher Education and Research, Mysuru, Karnataka, India-570015. Email Id: gsmeghana@jssuni.edu.in, Phone: 9972170593, ORCID ID:0000-0003-2384-4081

ABSTRACT

South Korea's cosmetics industry grew rapidly to USD 13.1 billion in domestic sales and USD 10.3 billion in exports by 2023, but post-market surveillance (PMS) has not kept pace with the risks this growth creates. Using three years of South Korea's Ministry of Food and Drug Safety (MFDS) data (2021–2023), five enforcement case studies, and an original Communication Effectiveness Index (CEI), this study evaluated whether safety information generated by enforcement actually reaches consumers. Enforcement performance improved substantially over the period: recall rates rose from 15.2% to 24.1%, and inspection turnaround shortened from 42 to 33 days. Yet the CEI revealed a 45-point communication gap between regulators (75) and consumers (30), with manufacturers (55) and healthcare professionals (49) falling in between. This gap, not enforcement capacity, is the central constraint: consumers remained nearly as exposed to risk information failures even as MFDS's technical performance strengthened. The five case studies illustrate how this breakdown occurs in practice, particularly where digital and influencer-driven sales channels outpace regulatory communication. The findings suggest that closing South Korea's cosmetics-safety gap requires investment in how risk information is delivered to consumers, not only in how violations are detected and enforced.

KEYWORDS: Post-market surveillance, cosmetics regulation, MFDS, risk communication, information asymmetry, cosmetovigilance.

INTRODUCTION

New cosmetics reach South Korean shelves faster than anyone can check them. Between 2021 and 2023 the domestic market grew 15.7% a year, from USD 9.8 billion to USD 13.1 billion; registered products rose from 128,400 to 159,300, and active manufacturers reached 9,420 [1]. Every one of those products entered a market where 71% of sales already happened online, and where most 18–35-year-olds said social media, not the regulator, shaped what they bought [2].

Pre-market approval was not built for this pace. It checks a formulation once, at launch, so it cannot know how a product behaves months later across different skin types [3]. Post-market surveillance (PMS) exists to catch what pre-market approval misses. South Korea's MFDS runs registration, inspection, complaint handling, recalls, and adverse event reporting, and on paper it is working: inspection cycles fell from 42 to 33 days and online product removals more than doubled [4]. But enforcement improving sharply while consumer-facing communication lags behind is exactly the gap this paper measures: a recall nobody hears about protects nobody.

Influencer content now reaches consumers faster and more persuasively than any MFDS notice. Consumers are left with plenty of claims and little reliable safety information, close to what Akerlof called 'information asymmetry' [5]. This study asks three things: how has Korea's cosmetics PMS performed since 2021, does safety information reach the people who need it, and where it doesn't, what would fix that?

Most PMS research is really pharmacovigilance research, where mandatory reporting is standard [6][7]; cosmetics-specific work has mostly catalogued what the rules require without testing whether the information reaches anyone [8][9]. That is the gap this paper closes, with an original Communication Effectiveness Index (CEI) that measures reach directly. South Korea is a useful test case precisely because it is a hard one: K-beauty's export scale, a market outgrowing the regulator's own inspection capacity, and a consumer base shaped more by social media than by any regulatory notice [2]. MFDS's hybrid model, sitting between the EU's mandatory approach and the historically voluntary US one (Table 4), also makes it a natural comparative midpoint. The Cosmetics Act was amended repeatedly across 2021–2023 to expand recall and inspection powers (4), and that trend has continued: a partial amendment (Act No. 21302, 30 December 2025) adds mandatory pre-market safety-assessment documentation on a 2028–2031 timeline, and a further rule change effective 2 April 2026 targets cross-border e-commerce cosmetics [10][11]. Every revision points the same direction this paper documents empirically: more inspection authority, with consumer-facing communication never named as a comparable priority [4, 12]. The study uses only public secondary data; no ethics approval was required, as no primary or identifiable human-participant data were collected (see Ethical Statement).

2. MATERIALS AND METHODS

This study combines quantitative trend analysis, case examination, and an original communication index, because no single method answers a question this broad on its own: numbers show what changed, and cases show why. Triangulating across all three, using a convergent synthesis design, grounds the findings while keeping them interpretable.

Quantitative data come from MFDS annual reports, inspection statistics, recall notices, and enforcement logs (2021–2023), cross-checked against Korea Consumer Agency (KCA) reports and trade press; adverse-event data come from the MFDS cosmetovigilance database. Market context comes from Statistics Korea (KOSTAT), the Korea International Trade Association (KITA), and the Korea Creative Content Agency (KOCCA). One caveat applies throughout: because MFDS-sourced figures, including Table 1, are self-reported by the regulator being evaluated, they carry the same reporting incentives this paper critiques on the consumer side.

Five enforcement cases were purposively sampled for contrasting product categories, risk types, and outcomes [13], and they map one-to-one onto the five violation categories in Table 2: prohibited substances (Case A), UV filter exceedance (Case B), allergen labeling (Case C), therapeutic claims (Case D), and para-phenylenediamine (PPD)/hair-dye exceedance (Case E), touching every category behind the 441 violations recorded in 2023. What they cannot do is stand in for the variation within each category, a limit revisited in Section 7.4.

The CEI is this study's central methodological contribution: a way to score, not assume, whether safety information reaches the people it is meant to protect. At this stage it is a promising first-pass instrument, not a validated one; criterion validation against an independent outcome measure has not yet been performed (Section 7.4). Its four sub-dimensions map onto constructs risk-communication research treats as jointly necessary for behavior change [14]: Timeliness (immediacy), clarity (format accessibility), transparency (source credibility), and engagement (channel fit and two-way reach). Each is scored 0–100 against a documented rubric. For timeliness, 0 means no dated communication, 50 means issued weeks late unexplained, and 100 means issued concurrently with the action; the composite is the unweighted mean of the four. Equal weighting was used because no validated weighting scheme exists for this context; a sensitivity check is planned before wider application. The parallel rubrics for clarity, transparency, and engagement follow the same logic but are not reproduced here in full, which limits independent replication until published in an appendix.

Both authors independently double-coded 20% of documents and compared agreement using Cohen's κ , yielding $\kappa = 0.81$ (95% CI 0.74–0.88), indicating strong inter-rater agreement on the CEI rubric. Criterion validity against an independent outcome measure has not yet been established, so this figure should be read as evidence of coding consistency rather than of the instrument's predictive validity. As an informal comparison, CEI rankings track the Section 7 narratives reasonably well: consumers' low scores align with Case A's partial recall compliance, and higher engagement scores with Case B's 94% return rate, though two cases cannot substitute for prospective validation. The next steps are a test–retest application to a second annual dataset and a criterion-validation study against an independent outcome measure such as product-return rates.

3. The Theoretical Framework

Every case here is read through a five-stage consumer-safety cycle: (1) Risk Emergence: a hazard appears in real use; (2) Signal Detection: MFDS catches it via complaints, inspections, or adverse event data; (3) Regulatory Intervention: MFDS acts, from label change to withdrawal; (4) Information Dissemination: that decision is communicated to manufacturers, healthcare professionals, and consumers; (5) Consumer Response: people actually change what they buy or do.

Stage 4 is where this paper's argument lives: a technically flawless Stage 2–3 response is worth little if Stage 4 fails. Case A shows this exactly: a competent recall consumer never heard about it, so contaminated stock stayed in use. Two feedback loops follow: a technical loop, where adverse event data sharpens detection, and a communicative loop, where consumer engagement generates that data in the first place. Case E shows the communicative loop working as intended, with clinician reports catching a dangerous hair dye before more people were hospitalized [15][16].

4. The Regulatory Environment And Market Context

PMS performance cannot be read apart from the market it has to keep pace with. Table 1 summarizes the core indicators for 2021–2023.

5. Quantitative Results

5.1 Overview (2021–2023)

Table 1 tells a two-track story. Enforcement improved steadily: recall rates rose from 15.2% to 24.1% (+58.6%), inspections sped up from 42 to 33 days, and penalty issuances climbed 41.3% to 441. But catching a problem and protecting a consumer are not the same thing. Adverse event reporting barely moved, 7.1% to 9.2%, meaning roughly nine in ten adverse cosmetic events still never reach MFDS. Digital monitoring nearly doubled to 44%, the biggest single gain in the table, yet it still misses more than half of a market that is 71% online. Recall responsiveness grew roughly twice as fast, in percentage terms, as adverse-event reporting over the same three years (58.6% vs. 29.6%), and that gap widened each year rather than narrowing. This is the paper's central pattern: enforcement improved sharply while consumer-facing communication did not keep pace.

5.2 Violation Category Analysis

Therapeutic claim violations doubled, from 31 to 62, as the line between a legal cosmetic claim and an illegal pharmaceutical one (cellular regeneration, collagen rebuilding) became a marketing tactic; none of the flagged products held pharmaceutical authorization [2]. Prohibited-substance detections rose 39.8%, to 179 cases [17]. A chi-square test of independence on the category-by-year counts (excluding the pending microbiological row) was not significant ($\chi^2 = 8.85$, $df = 8$, $p = 0.36$, Cramér's $V = 0.06$): the violation-category mix itself has not shifted detectably, which tempers the

therapeutic-claims finding without undermining it. The growth is real, but with only three annual points, the test is underpowered to confirm a structural realignment.

5.3 Communication Effectiveness Index

The scores form a clear ladder: MFDS 75, manufacturers 55, healthcare professionals 49, and consumers 30: a 45-point shortfall between the regulator and the public it is meant to protect. Healthcare professionals' score is the most underappreciated result here: dermatologists and pharmacists are the intermediaries consumers actually trust, yet MFDS has no systematic channel to them. On timeliness alone, MFDS scores 82 against consumers' 33; on engagement, 67 versus 29. Consumer communication is not built to invite reporting, which is exactly what keeps the reporting rate stuck near 9% [18].

5.4 Comparative Regulatory Framework Analysis

South Korea holds its own on enforcement speed and its pragmatic hybrid model but lacks an EU-style consumer portal or an FDA-style public recall database, and cosmetovigilance remains only partially mandatory. Even the FDA's own infrastructure is not fully unified: drug and device safety signals are tracked through separate systems, the FDA Adverse Event Reporting System (FAERS) and the Manufacturer and User Facility Device Experience database (MAUDE), that are not routinely cross-referenced. The US precedent is instructive: MoCRA (2022) converted the FDA's voluntary adverse-event system into a mandatory one (15-business-day reporting, safety-substantiation records), the first real change to US cosmetics law since 1938 [19]. That is essentially the reform this paper recommends for MFDS. The pattern across every comparison is the same: mature PMS systems invest as much in communication as in enforcement.

6. Case Studies In Pms Enforcement

Five matched cases, read against the five-stage framework and the CEI, translate the statistics into what actually happened on the ground.

Case A (2021): MFDS found betamethasone, an undeclared corticosteroid, in a whitening serum on sale for eight months. Consumers had posted about skin thinning throughout that period; none of it reached MFDS; this is the direct cost of a consumer CEI score of 30. The recall and ₩85 million penalty went to manufacturers and the regulatory gazette, never to the platforms where consumers actually found the product, so stock recovery stayed low [20].

Case B (2022): a tip-off via the EU's Rapid Alert System for dangerous non-food products (RAPEX) led MFDS to a children's sunscreen with excess benzophenone-3, already in an estimated 47,000 households via parenting social media. This time MFDS worked directly with parenting-community influencers. Result: a 94% return rate, against Case A's partial recovery. One contrasting pair cannot prove causation, but it is consistent with communication working better when it goes where the audience already is.

Case C (2022): an anti-aging cream lost its allergen declarations after a routine reformulation that never triggered a fresh check. Consumer complaints via the MFDS portal caught it; correction followed within 60 days. Reformulation, a routine business event, currently falls outside mandatory review.

Case D (2023): a toner marketed by micro-influencers reaching 4.2 million followers claimed to reverse skin aging at the cellular level, an unlicensed therapeutic claim [21]. MFDS ordered takedowns; the content resurfaced elsewhere within 72 hours, the clearest case here for AI-assisted digital surveillance.

Case E (2023): a hair dye with excess PPD caused three hospitalization-level reactions before dermatology clinics' adverse-event reports identified the cause. MFDS responded fully, with suspension, recall, and a criminal referral, but only because clinicians reported. It is the clearest argument in this paper for raising the 9.2% reporting rate: healthcare professionals are a force multiplier, not a peripheral channel.

7. DISCUSSION

7.1 Communication, Not Enforcement, Is The Binding Constraint

South Korea's biggest cosmetics-safety problem is not weak enforcement; it is weak delivery. The 45-point CEI gap between MFDS (75) and consumers (30) is a structural failure, not measurement noise, and it tracks exactly what risk-communication research predicts [14, 22]: source credibility, format accessibility, and channel fit all shape whether safety information changes behavior. MFDS's institutional sophistication (CEI 75) stops before it reaches consumers; the engagement gap (67 vs 29) shows consumer communication is not built to invite reporting or check understanding.

7.2 Digital Monitoring Has to Catch Up

Case D and the 44% digital monitoring figure make the same point from different angles [23, 24]: 71% of sales and most under-35 purchases happen online, so watching only 44% of that space misses more than half the market's influence on behavior. Natural language processing (NLP)-based monitoring already runs at the FDA and several EU authorities; MFDS has the legal authority to do the same, and the 85%+ target in Table 6 is realistic within 12–18 months. What is missing is prioritization, not capability.

7.3 Why a Third of Products Still Fail Inspection

A 38.6% violation rate still means roughly a one-in-three chance of encountering a non-compliant product. Therapeutic-claim violations track influencer-marketing incentives; prohibited-substance violations look more like genuine supply-chain gaps: different problems needing different fixes. With 9,420 active manufacturers, many small [25, 26], a tiered compliance system is more likely to move this number than tougher enforcement alone.

7.4 Limitations

The CEI is new and needs longitudinal, cross-national testing. The quantitative data are self-reported by MFDS and carry that bias. The five cases are illustrative, not a statistical sample of the enforcement record. Consumer surveys, manufacturer interviews, and a repeat CEI application would all strengthen what is reported here.

7.5 Theoretical and Practical Implications

This paper extends Akerlof's information asymmetry (5) and Stiglitz and Weiss's regulatory extension [27] into a measurable regulatory-performance construct: the CEI turns “asymmetry” into a scoreable gap between stakeholder tiers. It also makes Stage 4 (Information Dissemination) empirically testable in its own right, rather than an implicit outcome of enforcement. The chi-square result in Section 5.2 is at least not inconsistent with that separation, though underpowered to confirm it outright. Practically, the CEI gives MFDS a diagnostic it can re-run annually with data it already collects, targeting whichever sub-dimension is weakest for a given stakeholder (Table 3: engagement for consumers, transparency for manufacturers) rather than funding generic “communication improvement.” Nothing in its four sub-dimensions is Korea-specific, so the same logic travels to any PMS system with its own inspection logs and complaint records.

8. Policy Recommendations

Seven concrete actions, each with a KPI, timeline, and lead body, built around one idea: consumer protection needs as much investment in reaching people as in catching violations.

Digital Surveillance means NLP classifiers trained on unlicensed therapeutic-claim language, undeclared ingredients in reviews, and out-of-spec filter/allergen claims, rolled out two platforms per quarter. Consumer communication means pushing recall alerts to the parenting and beauty communities the CEI shows consumers already trust (the route Case B used to reach a 94% return), not a static gazette page. HCP Engagement means scoring cosmetovigilance reporting within dermatologists' and pharmacists' existing CPD requirements, closing the gap between their 49 CEI score and the trust consumers place in them. Influencer regulation means a platform-enforced disclosure label triggered by the same keyword set the surveillance classifiers use, so detection and disclosure share one technical backbone [21]. Three principles tie all seven together: communication should be resourced like enforcement, not treated as an afterthought [14]; reform should be co-designed with consumers; and Korea's USD 10.3 billion K-beauty export position gives it real standing to lead a regional PMS intelligence-sharing network.

9. CONCLUSION

South Korea's cosmetics PMS genuinely improved between 2021 and 2023: recall responsiveness up 58.6%, inspections 21.4% faster, and digital monitoring nearly doubled to 44%. That investment is real. But a 38%+ violation rate, doubled therapeutic-claim violations, an adverse event reporting rate stuck under 10%, and a consumer CEI score of 30 add up to something enforcement alone cannot fix. A PMS system's real value is not the sophistication of its detection; it is how much of the population actually benefits from what it detects. The five-stage framework and the CEI, together with the seven recommendations in Table 6, turn that diagnosis into a program a market as globally influential as K-beauty is well placed to lead on.

Addendum: Emerging Signals from 2024–2025

MFDS reports needed to extend Table 1 and the CEI to 2024–2025 were not publicly available at the time of writing, so the analysis stays scoped to 2021–2023. Public signals point the same direction: recalls and disposals rose from five in 2024 to sixteen in 2025, exports reached a record US\$11.4 billion in 2025 [28], and MFDS's own January 2025 policy statement names expanded inspection, not consumer communication, as its priority, consistent with, though not a formal extension of, the pattern documented here.

Ethical Statement: This study used only secondary data from public sources (MFDS, KOSTAT, KCA, KITA, KOCCA). No primary or identifiable human-participant data were collected, so no IEC/IRB approval was required.

Patient Consent: NA

Conflict of Interest: The authors declare no commercial or financial relationships that could be construed as a conflict of interest. JSS College of Pharmacy has no institutional or commercial interest in the bodies, companies, or products discussed.

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Data Availability: All quantitative data are publicly available (www.mfds.go.kr; www.kcia.or.kr; kosis.kr; www.kita.net). The CEI instrument is described in Section 2 and available from the corresponding author on reasonable request.

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Tables and Figures

Table 1: South Korea Cosmetics PMS Performance Indicators, 2021–2023 (Source: MFDS Annual Regulatory Reports; MFDS Cosmetovigilance Surveillance Dataset)

Performance Indicator	2021	2022	2023	% Change
Product Recall Rate (%)	15.2	19.8	24.1	↑ 58.6

Regulatory Violation Rate (%)	50.3	44.7	38.6	↓ 23.3
Adverse Event Reporting Rate (%)	7.1	8.4	9.2	↑ 29.6
Average Inspection Cycle (days)	42	38	33	↓ 21.4
Consumer Complaint Resolution (%)	61.0	66.5	71.3	↑ 16.9
Digital Platform Monitoring (%)	23.0	31.0	44.0	↑ 91.3
Manufacturer Penalty Issuances (n)	312	387	441	↑ 41.3
Online Product Removals (n)	1,842	2,617	3,904	↑ 111.9
Recall Notices Issued (n)	78	103	129	↑ 65.4
Import Products Flagged (n)	214	289	347	↑ 62.1
Cosmetovigilance Reports Processed (n)	4,320	5,108	6,271	↑ 45.2
Healthcare Professional Reports (n)	319	405	498	↑ 56.1

Figure 1. South Korea Cosmetics PMS Performance Trends, 2021-2023

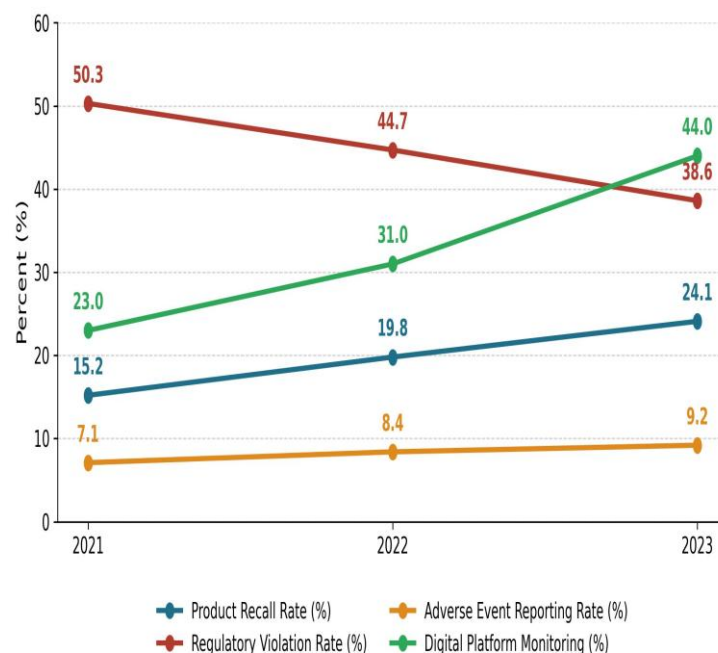


Figure 1. South Korea Cosmetics PMS performance trends, 2021–2023 (Table 1). Enforcement-side indicators rise faster than adverse event reporting, which stays under 10% throughout; this is the visual signature of the divergence discussed above.

Table 2: Cosmetics Regulatory Violation Categories, South Korea 2021–2023 (Source: MFDS Enforcement Action Logs; Recall Notices Database)

Violation Category	2021	2022	2023	Change	Primary Segments
Prohibited Substances	128	164	179	↑ 39.8%	Skin whitening, anti-ageing serums
UV Filter Concentration Exceedance	54	71	89	↑ 64.8%	Sunscreens (adult and children)
Allergen Label Omission	87	93	104	↑ 19.5%	Fragranced moisturisers, hair care
Therapeutic Claim Violations	31	47	62	↑ 100.0%	Toners, essences (influencer-marketed)
PPD / Hair Dye Exceedance	12	12	7	↓ 41.7%	Professional and DTC colourants
Microbiological Non-compliance	—	—	—	Pending	All categories
Total Violations Recorded	312	387	441	↑ 41.3%	All categories

Figure 2. Cosmetics Regulatory Violations by Category, South Korea 2021-2023

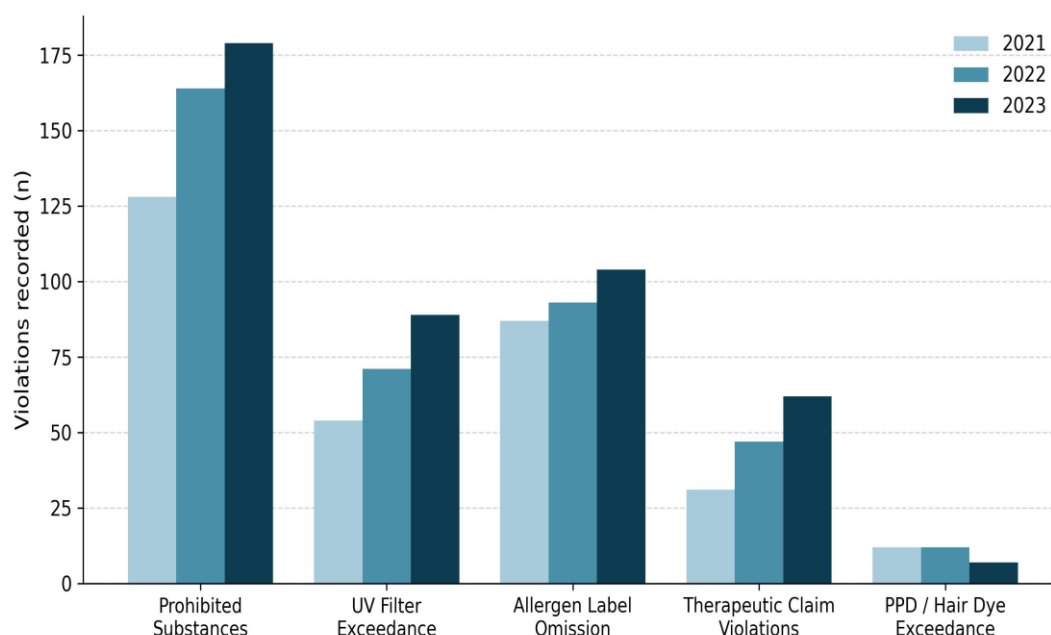


Figure 2. Cosmetics regulatory violations by category, South Korea, 2021–2023. Therapeutic claims show the steepest proportional rise (+100%); PPD/hair-dye exceedance is the only category to fall.

Table 3: Communication Effectiveness Index (CEI) by Stakeholder Group, 2023 (preliminary application; inter-rater reliability $\kappa = 0.81$, criterion validity testing pending, Section 2)

Stakeholder Group	Timeliness	Clarity	Transparency	Engagement	CEI Composite
Regulatory Authorities (MFDS)	82	78	74	67	75
Manufacturers / Industry Bodies	61	58	49	52	55
Healthcare Professionals	54	51	46	45	49
General Consumers	33	31	27	29	30

Figure 3. Communication Effectiveness Index (CEI) by Stakeholder Group and Sub-Dimension, 2023

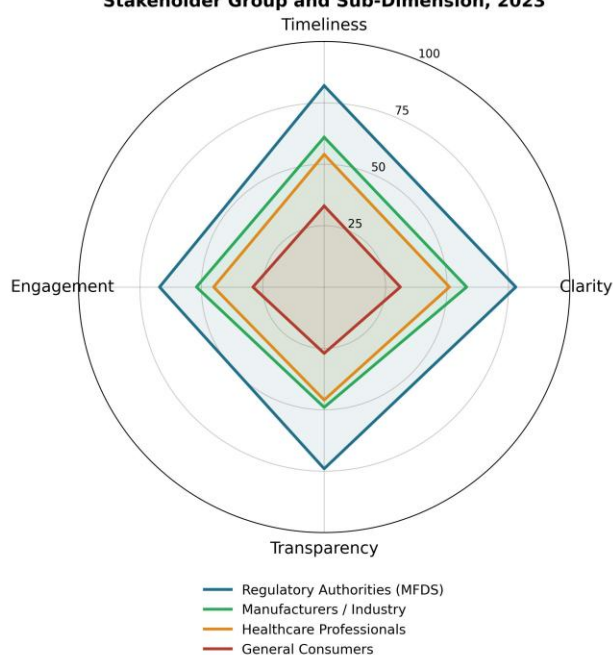


Figure 3. CEI by stakeholder group and sub-dimension, 2023. A consistent gradient (regulator > manufacturer > healthcare professional > consumer) runs across all four sub-dimensions.

Table 4: Comparative Cosmetics PMS Regulatory Frameworks (Sources: MFDS; European Commission; US FDA; Choi, 2023). Note: the EU and US Consumer CEI scores are illustrative estimates drawn from the comparative literature cited above, not computed via the CEI instrument applied to MFDS data in Table 3; they should be read as indicative benchmarks rather than directly comparable measurements.

Regulatory Dimension	South Korea (MFDS)	European Union	United States (FDA)
Regulatory Model	Mixed Pre/Post-Market	Harmonised PMS Mandate	MoCRA (2022): Post-Market Emphasis
Adverse Event System	MFDS Reporting Portal	RAPEX + EudraVigilance	MedWatch/CFSAN AER; mandatory 15-day serious-AE reporting under MoCRA
Recall Transparency	Moderate (partial public)	High (full RAPEX disclosure)	Very High (FDA public DB)
Digital Monitoring	Emerging: 44% coverage	Advanced: integrated AI	Advanced: AI + NLP
Consumer CEI Score	30 (Low)	52 (Moderate)	61 (Moderate–High)
Enforcement Speed (avg. days)	33 days (improving)	Variable (15–60 days)	Variable (21–90 days)
Mandatory Cosmetovigilance	Partially mandatory	Fully mandatory (RP obligation)	Mandatory since MoCRA; voluntary before
Cross-border Intelligence	Limited (bilateral MOUs)	RAPEX + SCCS network	FDA–Health Canada MRA
SME Compliance Support	Limited guidance	Structured tiered support	SME-specific FDA portal

Table 5: Selected Cosmetics PMS Enforcement Cases, South Korea 2021–2023

Case	Product	Risk Identified	Regulatory Action	Outcome	Communication Outcome
A (2021)	Skin Whitening Serum	Undeclared betamethasone	Recall + penalty (₩85M)	Partial; stock unrecovered	Stage 4 failure: no consumer broadcast
B (2022)	Children's Sunscreen	UV filter exceedance	Full withdrawal + influencer alert	94% product return	Multi-channel strategy effective
C (2022)	Anti-Ageing Cream	Allergen under-declaration	Label revision + audit	Compliance in 60 days	Consumer advisory; moderate reach
D (2023)	Influencer-Marketed Toner	Unlicensed therapeutic claims	Platform takedown	Partial; cross-platform migration	Digital protocols still forming
E (2023)	Hair Dye Formulation	PPD exceedance; 3 hospitalisations	Suspension + criminal referral	Full removal; prosecution	HCP reporting central

Table 6: Strategic Recommendations for Enhancing PMS Effectiveness, with KPI Targets and Implementation Horizons

Strategic Area	Recommended Action	Target KPI	Horizon	Lead Body
Digital Surveillance	NLP-powered monitoring across 8 major platforms	Coverage: 44% → 85%+	12–18 months	MFDS Digital Division + KISA
Consumer Communication	Multilingual dashboard with real-time recall alerts	Consumer CEI: 30 → 55+	18–24 months	MFDS + MOH Consumer Protection
Adverse Event Reporting	Mobile-first simplified AER portal	AER rate: <10% → 25%+	12–18 months	MFDS IT Bureau + UX Team
SME Compliance Support	Tiered incentive framework, subsidised testing	Violation rate: 38.6% → <25%	24–36 months	MFDS Compliance Dept. + KCA
Cross-border Intelligence	APAC regulatory intelligence network (MoU)	Import flags resolved 40% faster	24–36 months	MFDS International Affairs
HCP Engagement	Mandatory cosmetovigilance CPD for dermatologists	HCP CEI: 49 → 65+	12 months	MFDS + Korean Dermatology Society

Influencer Regulation	Mandatory safety claim disclosure labelling	Therapeutic violations ↓ 50%	18 months	MFDS + KCC
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KISA = Korea Internet & Security Agency; MOH = Ministry of Health and Welfare; KCC = Korea Communications Commission.