

Heavy Metals in Skin-Lightening Cosmetics in India: Regulatory Standards, Unauthorized Imports, E-Commerce Non-Compliance, and Post-Market Surveillance

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Abstract

Objective: To explain why skin-lightening cosmetics containing toxic metals continue to reach Indian consumers despite legal controls, and to propose a practicable, risk-based surveillance model.

Significance of review: India combines a socially driven market for complexion-altering products with decentralized manufacture, small-parcel trade, and changing online listings. Existing reviews rarely follow products from manufacture or import through enforcement and recall.

Key findings: The Cosmetics Rules, 2020 prohibit intentional lead and arsenic colorants, limit unintentional mercury in finished non-eye cosmetics to 1 ppm, require import registration, prescribe labeling and sampling procedures, and provide for voluntary recall. Nevertheless, Indian studies and clinical reports identify mercury in marketed products and mercury-associated nephropathy. Persistence is best explained by a control-system mismatch: registration is disconnected from online listing verification; small parcels and third-country routing can bypass import controls; seller identities are mutable; surveillance is episodic; regulatory data are fragmented between central, state, customs, consumer, and platform systems; and adverse-event and recall arrangements do not create a visible feedback loop. Results require interpretation because deliberate mercury adulteration differs from unavoidable trace contamination by lead, arsenic, cadmium, chromium, or nickel.

Conclusions: India should establish a searchable product and responsible-person register, require platforms to verify registration before listing imported cosmetics, apply risk-scored online and border sampling, use validated X-ray fluorescence screening followed by confirmatory ICP-MS or equivalent methods, mandate serious cosmetic adverse-event reporting and recall effectiveness checks, and publish interoperable alerts in real time. Enforcement should prioritize products with absent provenance, skin-lightening claims, rapid relisting, or prior international alerts.

Keywords: skin lightening; mercury; lead; arsenic; cadmium; cosmetics regulation; CDSCO; e-commerce; post-market surveillance; India

1. Introduction

Skin-lightening products occupy an unusual regulatory space. They are ordinary consumer goods in presentation, are often used chronically on large body-surface areas, and may be promoted with quasi-

therapeutic claims about melanin, acne, melasma, or pigmentation. Their risk therefore depends on composition, pattern of use, and the integrity of the supply chain. In India, these products are sold through established brands, neighborhood retailers, beauty channels, social media, marketplace platforms, and informal cross-border networks. The same product name can describe a compliant formulation, a diverted foreign product, a counterfeit, or a relabeled cream with no verifiable manufacturer.

Mercury is the clearest sentinel hazard because inorganic mercury salts suppress melanogenesis and can produce rapid visible effects, while chronic exposure can injure the kidney and nervous system and contaminate the household environment [1-7]. Lead, arsenic, and cadmium are more often contaminants of pigments or mineral raw materials, although deliberate use or gross contamination cannot be excluded. Chromium, nickel, cobalt, and antimony are relevant because of sensitization, systemic toxicity, or their occurrence in colorants and mineral ingredients [8-13]. The analytical and legal questions are therefore not interchangeable: a product containing thousands of milligrams per kilogram of mercury presents a different regulatory inference from a pigment-containing cosmetic with low-level lead close to an impurity limit.

The Indian framework is often described as weak simply because non-compliant products are found. That diagnosis is incomplete. The Cosmetics Rules, 2020 establish standards, licensing, import registration, labeling, inspection, sampling, laboratory analysis, stop-sale powers, and voluntary recall [14-18]. The more important question is why these controls fail to operate as a continuous system once a product is sold by a mutable online seller, shipped in small parcels, or lacks a responsible Indian entity. This review follows the complete pathway from manufacture and import to consumer use, surveillance, reporting, and recall. It combines legal analysis with occurrence studies, clinical evidence, analytical science, and international regulatory practice. Its purpose is not to estimate a national prevalence—which current evidence cannot support—but to identify where control signals are lost and how they can be reconnected.

2 Review approach and scope

A structured narrative review was undertaken to support regulatory analysis. Searches covered PubMed, publisher databases, official Indian sources, and international regulator and treaty websites. Concepts combined terms for skin lightening or whitening, cosmetics, mercury, lead, arsenic, cadmium, chromium, nickel, India, import, e-commerce, registration, surveillance, recall, adverse event, and analytical methods. Priority was given to the Drugs and Cosmetics Act, the Cosmetics Rules, CDSCO guidance and notices, BIS-linked standards, official consumer and e-commerce rules, the Minamata Convention, WHO documents, peer-reviewed studies, clinical case reports, and regulator alerts. Recent material was emphasized, while older landmark studies were retained where they defined exposure, clinical syndromes, or analytical practice.

This is a regulatory review rather than a systematic prevalence meta-analysis. Heterogeneity in sampling frames, product definitions, digestion methods, limits of detection, metal species, units, and purchase channels makes pooled Indian prevalence inappropriate. Marketplace studies based on convenience samples can identify hazards but cannot establish the proportion of all products that are unsafe. News reports were used only to describe recent enforcement episodes when a primary notice was unavailable and are identified as such.

3 Hazard, exposure, and public-health significance

3.1 Mercury as an intentionally effective toxicant

Inorganic mercury salts can inhibit tyrosinase and reduce melanin formation, explaining both their efficacy and their persistence in illicit formulations. Dermal absorption varies with species, formulation, skin integrity, frequency, and occlusion. Exposure is not limited to the user: mercury can transfer to hands, bedding, surfaces, wastewater, and household dust, creating secondary exposure. The global systematic review by Bastiansz et al. identified 41 eligible studies from 22 countries, 787 products, and 1,042 biomarker measurements; the pooled product distribution was highly skewed, consistent with a market containing many low results and a smaller group of extreme adulteration [3]. This heterogeneity makes median values poor reassurance for high-risk submarkets.

Renal injury is the most consistently reported severe outcome. Mercury can trigger proteinuria, minimal-change disease, membranous nephropathy, and autoantibody-associated disease. Indian reports of mercury-associated membranous nephropathy linked several patients to the same cream; product testing found concentrations in the thousands of parts per million [6,7]. Neurologic irritability, tremor, memory and mood disturbance, peripheral sensory symptoms, gingivostomatitis, and dermatologic irritation are also described [2,4,5]. Biomonitoring may involve urine mercury for inorganic exposure, but interpretation requires exposure history, timing, renal status, and specialist input. Chelation decisions are clinical and should not be inferred from a cosmetic test alone.

3.2 Lead, arsenic, cadmium, and other metals

Lead has no useful role in a skin-lightening cream and may enter through pigments, mineral fillers, contaminated equipment, or poor-quality raw materials. Chronic exposure is neurotoxic and hematotoxic, with particular concern during pregnancy and childhood. In adults, the incremental contribution of dermal cosmetic exposure is difficult to quantify because gastrointestinal intake after hand-to-mouth transfer and oral exposure from lip products may dominate. Arsenic contamination may originate from minerals or botanical materials and raises carcinogenic and systemic concerns. Cadmium is nephrotoxic and accumulative; nickel, chromium, and cobalt are prominent contact allergens, and hexavalent chromium has additional toxicologic significance [8-13,19].

Risk interpretation must separate concentration from dose. A total-metal concentration above a regulatory specification establishes non-compliance but does not by itself quantify systemic risk. Conversely, a concentration below a generic limit is not automatically safe for every use pattern. Leave-on facial use, damaged skin, prolonged use, application during pregnancy, and simultaneous use of multiple products may increase exposure. A defensible assessment reports sampling design, product mass used, frequency, exposed area, retention factor, dermal absorption assumptions, body weight, uncertainty, and whether the analytical result is total or bioaccessible metal [10-13,20].

3.3 Social and commercial drivers

Demand is sustained by colorism, gendered beauty norms, perceived employment and marriage advantages, and the medicalization of normal variation in skin tone. A Mumbai survey documented widespread engagement with fairness products and linked use to social meanings of skin color [21]. Marketing has shifted from the explicit language of 'fairness' toward 'brightening', 'radiance', 'anti-spot', and 'glow', but the underlying expectation may remain pigment alteration. Regulatory surveillance based only on the term 'whitening' will therefore miss semantically adjacent claims and multilingual listings.

Table 1. Toxic metals relevant to skin-lightening cosmetics and regulatory interpretation

Metal	Likely route into product	Principal concern	Regulatory interpretation
Mercury	Deliberate depigmenting agent; contaminated raw material	Renal and neurologic toxicity; household contamination	>1 ppm in non-eye finished cosmetics is non-compliant; high concentrations strongly suggest intentional addition
Lead	Pigments, minerals, equipment, environmental contamination	Neurotoxicity, hematotoxicity, reproductive risk	Lead compounds prohibited as colorants; interpret limits in their stated regulatory context
Arsenic	Minerals, pigments, botanicals, water	Carcinogenicity and systemic toxicity	Arsenic compounds prohibited as colorants; investigate source and raw-material control
Cadmium	Pigments and mineral impurities	Renal, skeletal, and carcinogenic risk	Needs product-specific risk assessment and clearer surveillance specifications
Chromium / nickel / cobalt	Pigments, minerals, equipment	Allergic contact dermatitis; metal-specific systemic concerns	Useful indicators of raw-material quality and sensitization risk

4 Indian regulatory architecture

4.1 Division of authority

The Drugs and Cosmetics Act, 1940 provides the statutory foundation, while the Cosmetics Rules, 2020 consolidate the operational regime [14,15]. CDSCO and the Central Licensing Authority control import registration and central functions; State Licensing Authorities license domestic manufacture and conduct much of the market-level inspection and enforcement. Customs and designated port officers control consignments at entry. Government Analysts, the Central Cosmetic Laboratory, and approved laboratories support legal testing. Consumer authorities, the Central Consumer Protection Authority, customs intelligence, cybercrime units, and e-commerce platforms possess information or powers that affect the same products, but they do not operate as a single surveillance network.

This divided structure is rational at the formal level but creates hand-offs. A state inspector may find an imported cream without access to a real-time, machine-verifiable registration record. CDSCO may issue an alert without a standardized product identifier that platforms can match across altered images and seller accounts. Customs may assess a declared consignment while direct-to-consumer parcels arrive under generic descriptions. The principal regulatory gap is therefore not absence of actors; it is absence of shared identifiers, interoperable evidence, and time-bound response duties.

4.2 Standards for metals and prohibited ingredients

Rule 39 requires cosmetics to comply with Ninth Schedule specifications or other applicable quality and safety standards. Materials in Annex A of IS 4707 Part 2 may not be added. Permitted synthetic and natural organic colors are limited to 2 ppm arsenic calculated as arsenic trioxide, 20 ppm lead, and 100 ppm total heavy metals other than lead. The Rules separately permit mercury up to 70 ppm as a preservative in eye-area cosmetics and cap unintentional mercury in other finished cosmetics at 1 ppm. Lead and arsenic compounds may not be used to color cosmetics [15-17].

These provisions are frequently oversimplified. The 2/20/100 ppm limits are expressed in the context of permitted colors, not as a universal authorization to formulate any finished cosmetic with those amounts. The 1 ppm mercury provision for non-eye finished products is expressly an unintentional limit. A skin-lightening cream with mercury added for depigmentation is not legitimized by describing mercury as an impurity. Regulators should interpret composition, concentration, labeling, manufacturing plausibility, and product claims together. Cadmium does not receive the same clear finished-product numeric treatment in the quoted rule text, which strengthens the case for modern contaminant specifications by product type and raw-material risk.

4.3 Domestic manufacture

Domestic manufacturers require a State licence or loan licence, must self-declare compliance with good manufacturing practices, maintain technical staff and records, and submit to inspection. The Rules contemplate inspection within 30 days after grant and inspection of licensed premises at least once in three years, while licence conditions are assessed periodically [15]. For metals, effective control begins with supplier qualification, identity testing of mineral and botanical raw materials, validated cleaning, prevention of cross-contamination, batch specifications, and investigation of atypical trends—not merely an end-product certificate.

A documentation-led licence system is vulnerable when certificates of analysis are copied, methods are unsuitable, or representative sampling is absent. CDSCO's published list of import-registration deficiencies specifically notes missing or non-compliant test reports for mercury, lead, arsenic, and other heavy metals [17]. Equivalent scrutiny is needed for domestic supply chains. Risk-based inspection should focus on manufacturers using high-risk pigments, talc, clays, traditional mineral ingredients, or private-label contract networks, and on products making rapid or dramatic lightening claims.

4.4 Import registration and border control

No cosmetic may be imported unless registered. Form COS-1 is used to obtain a COS-2 registration certificate for the product, variants, and manufacturing site; a separate importer may obtain an import registration number through COS-4/COS-4A for a product already registered under the Rules [15-18]. Imported labels must carry the registration certificate number and Indian importer information. Customs receives a compliance declaration. If a port officer suspects contravention, samples may be taken and the consignment detained pending laboratory results.

This architecture is strongest for formal commercial consignments and weakest for undeclared, misdeclared, postal, courier, traveler, or third-country movements. Small-parcel trade changes the denominator: instead of a limited number of importers and consignments, regulators face a large stream of low-value parcels linked to short-lived sellers. A foreign label can also be hidden by an over-sticker, marketplace image, or fulfillment packaging. The 2026 reports concerning unauthorized Pakistani-origin creams sold in India, and contemporary reporting that internationally alerted creams could be purchased

through an Indian marketplace, illustrate how prohibited origin, absent registration, excessive metals, and platform relisting can converge [22,23]. These reports are enforcement signals, not prevalence estimates.

4.5 Labeling, claims, and classification

Labels must identify the product and manufacturer, provide batch and expiry information, ingredient declarations, and required hazard directions; imported unit packs must state the registration certificate number and importer. False or misleading claims are prohibited [15]. The label is thus both a communication instrument and a traceability device. Absence of a batch number, responsible Indian address, or RC number should be treated as a high-priority surveillance trigger rather than a minor documentary defect.

Claim-based classification remains difficult. A product that merely beautifies is a cosmetic, while claims to treat disease or alter body structure or function may move the product toward drug regulation. Online sellers can make stronger claims than the physical label and can change them instantly. Evidence capture must therefore preserve the listing URL, seller ID, screenshots, claim text, transaction invoice, product images, and received sample. Regulators should assess the marketed presentation as a whole rather than the container alone.

Table 2. Indian control pathway and failure points

Stage	Primary control	Observed or plausible failure	Priority correction
Manufacture	State licence, GMP, records, inspection	Weak supplier controls; document dependence; infrequent risk targeting	Raw-material risk tiers, trend review, targeted inspection
Import	COS-2 registration, declaration, port sampling	Small parcels, misdeclaration, third-country routing	API verification, parcel risk rules, international alert watchlists
Market entry	RC number, importer and batch labeling	Missing/false identifiers; unverifiable labels	Public product register and label-image matching
E-commerce	Seller disclosure and grievance duties	Rapid relisting, image obfuscation, seller churn	Pre-list verification, image hashing, network enforcement
Consumer use	Warnings and ingredient list	Undeclared toxicant; chronic exposure; delayed injury	Targeted education and easy product-linked reporting
Surveillance	Inspector sampling and Government Analyst testing	Episodic sampling; fragmented data; turnaround delay	National risk plan, XRF triage, shared LIMS
Action / recall	Stop-sale, seizure, voluntary recall, alerts	No accountable importer; low recall visibility; clone listings	Mandatory duties, purchaser notification, effectiveness checks

5 Unauthorized imports and e-commerce non-compliance

5.1 How the online market defeats static controls

E-commerce increases legitimate access but lowers the cost of regulatory evasion. A seller can reach a national market without a conventional distribution network, replace a delisted item with a new stock-keeping unit, obscure the brand in an image, translate or soften claims, and use fulfillment services that separate inventory from the seller's legal address. Search ranking and recommendation systems can amplify a hazardous item before a regulator detects it. Removal of one listing does not remove linked inventory, clones, affiliate pages, social-commerce posts, or cross-border offers.

The Consumer Protection (E-Commerce) Rules, 2020 require marketplace entities to display seller information and establish grievance processes, while product safety obligations continue to arise under sector-specific law [24,25]. These horizontal duties are valuable but do not substitute for cosmetic registration verification. A platform can display the name supplied by a seller yet still have no reliable proof that the exact imported product, manufacturing site, and variant hold a valid COS-2 registration. The regulatory question should be binary and machine-checkable at listing: is this specific imported cosmetic linked to a valid registration and accountable Indian entity?

5.2 Unauthorized, counterfeit, and non-compliant are not synonyms

Enforcement records should distinguish at least four categories. An unauthorized import lacks the required registration even if composition is acceptable. A substandard cosmetic fails an applicable specification. A misbranded product has prohibited or deficient labeling or claims. A counterfeit or spurious product misrepresents identity or origin. A single cream may fall into several categories, but collapsing them obscures root causes and remedies. Registration verification addresses authorization; chemical testing addresses composition; forensic packaging and supply-chain investigation address authenticity.

This taxonomy also protects sound inference. A high mercury result in an item bearing a known brand does not prove that the brand owner manufactured it. Investigators should retain chain of custody, compare security features and batch records, contact the stated manufacturer, and document the seller and payment trail. Public alerts should include photographs, batch or lot details, declared origin, seller identifiers where lawful, test method, measured concentration, legal basis, and whether authenticity was confirmed.

5.3 The relisting problem

Global investigations show that mercury-containing lighteners persist online despite regulatory lists and platform policies [26-29]. The key mechanism is adversarial adaptation: sellers alter spelling, crop or blur images, use generic titles such as 'beauty cream', bundle products, or migrate between accounts. Keyword blocking alone will underperform. Platforms need image hashing, optical character recognition, fuzzy brand matching, seller-network analysis, and matching against regulator-provided product images and identifiers. Human review is still necessary because automated controls can over-remove legitimate products or miss regional-language euphemisms.

6 Analytical testing and interpretation

6.1 Sampling design

The scientific validity of surveillance begins before the laboratory. A risk-based program should stratify by channel, claim, price, origin, registration status, product form, seller history, and prior alerts. Duplicate purchases from independent sellers help separate batch-level formulation from isolated counterfeit distribution. Online samples should be purchased through controlled accounts and documented from

listing to delivery. Investigators should retain an unopened reserve sample and record mass, packaging, batch, expiry, seller, invoice, delivery route, and condition.

National estimates require probability-based sampling or explicit weighting. Convenience sampling should be described as hazard identification. Studies should avoid presenting 'percentage positive' without the analytical reporting limit and denominator. Non-detects, results below quantification, and results below regulatory thresholds are distinct. Units must be harmonized: for creams, mg/kg is numerically equivalent to ppm by mass, whereas mg/L is not interchangeable without density.

6.2 Screening and confirmatory methods

Portable or benchtop X-ray fluorescence can rapidly triage mercury, lead, arsenic, and other elements with minimal preparation and is valuable for high-throughput enforcement [30-33]. Its performance depends on calibration, geometry, matrix, container thickness, homogeneity, and detection limits. XRF is best treated as a screening tool. Regulatory confirmation should use a validated method such as acid digestion followed by inductively coupled plasma mass spectrometry (ICP-MS), ICP optical emission spectrometry, graphite-furnace atomic absorption, or cold-vapor atomic absorption/fluorescence for mercury [10,30-36]. Method validation should address selectivity, linearity, range, recovery, precision, limit of detection, limit of quantification, dilution integrity, carryover, digestion completeness, and measurement uncertainty. Certified reference materials or matrix-matched quality controls are critical; cosmetic creams contain oils, waxes, pigments, and emulsifiers that challenge digestion. Each batch should include blanks, spikes, duplicates, and continuing calibration verification. Laboratories should participate in proficiency testing and report the expanded uncertainty near decision limits. Speciation is rarely necessary to establish gross mercury non-compliance, but it can clarify toxicokinetics and source in research or complex cases.

6.3 From a result to a regulatory decision

A decision rule should be specified before testing. For a measured mercury concentration near 1 mg/kg, uncertainty can determine whether non-compliance is established. For concentrations hundreds or thousands of times higher, the conclusion is robust, and immediate risk management should not wait for exhaustive source attribution. Screening thresholds may be set conservatively below legal limits to minimize false negatives, with confirmatory testing before final enforcement. Laboratory reports should state the legal comparator and whether the result represents total mercury, calculated metal, or another expression used in the rule.

Table 3. Minimum analytical quality requirements for enforcement testing

Element	Minimum expectation	Reason
Sampling	Document listing, seller, invoice, label, batch, chain of custody; retain reserve	Links the laboratory result to the marketed product and supports legal action
Preparation	Validated homogenization and complete digestion for cream matrix	Prevents false low results and poor reproducibility
Screening	Matrix-verified XRF with conservative trigger levels	Enables high-throughput prioritization without treating screening as final proof

Element	Minimum expectation	Reason
Confirmation	ICP-MS/ICP-OES/GFAAS or validated mercury-specific method	Provides quantitative, defensible result
Quality control	Blanks, spikes, duplicates, CRM, calibration checks, proficiency testing	Demonstrates control of contamination, recovery, precision, and bias
Decision rule	Report uncertainty and comparator in the units/expression used by law	Avoids arbitrary decisions near the limit

7 Evidence from India and comparable markets

Indian evidence is sufficient to establish hazard but insufficient to estimate national prevalence. A Centre for Science and Environment investigation reported detectable mercury in 14 of 32 fairness creams sampled in Delhi markets, a finding subsequently discussed in government and medical reporting [37,38]. A Kerala study used ICP-MS to examine four commonly used creams for arsenic, lead, and mercury [39]. An exposure-flow analysis concluded that mercury entering India through high-mercury imported creams could be substantial even at modest tonnage and identified imported products as a sensitive control point [40]. A 2021 study of bestselling Indian fairness creams found extensive fragrance and allergen labeling but did not find mercury or certain pharmacologically active lighteners declared on labels—an important reminder that ingredient lists cannot exclude undeclared contaminants or adulterants [41].

Clinical evidence provides a separate line of inference. Indian nephrology reports have associated skin-lightening cream use with membranous nephropathy, including NELL-1-positive disease, and confirmed very high mercury in implicated products [6,7,42]. These are sentinel cases rather than incidence estimates. Their regulatory value is high because they connect product, exposure, biomarker or clinical phenotype, and laboratory confirmation. A national cosmetovigilance pathway should be designed to capture exactly this chain.

International studies show the same pattern at larger scale: compliant mainstream products coexist with small clusters of extreme mercury adulteration, especially in informal and online channels [3,26-29,43-47]. A recent multi-country Asian study measured mercury, lead, arsenic, cadmium, antimony, chromium, and nickel in face and eye cosmetics and found extreme heterogeneity, including very high mercury in facial creams and elevated arsenic in some eye cosmetics [48]. These results support targeted surveillance, but country averages should not be transferred to India without attention to product and channel composition.

8 Post-market surveillance, reporting, recall, and enforcement

8.1 Existing legal tools

Inspectors may sample cosmetics manufactured, imported, stocked, or exhibited for sale when contravention is suspected. Samples are sealed and sent to a Government Analyst; the Rules specify forms, reports, and a nominal 60-day analytical period, subject to justified extension. Inspectors can order that stock not be disposed of, and sale contrary to that order is prohibited [15]. A purchaser may also apply for analysis using Form COS-13 and receive a report in Form COS-14. These provisions create a legally defensible evidence pathway.

Rule 65 requires a manufacturer or authorized agent that believes a cosmetic may be unsafe to initiate withdrawal and inform the appropriate licensing authority [15]. Import undertakings also require reporting of foreign market withdrawals, restrictions, authorization cancellations, and not-of-standard-quality findings [15-18]. The weakness is that the primary recall provision is manufacturer-initiated. Unauthorized products may have no cooperative manufacturer or authorized agent in India, and a marketplace seller may disappear. Stop-sale, seizure, platform removal, public warning, and prosecution can therefore matter more than a conventional voluntary recall.

8.2 Cosmetovigilance and consumer reporting

India does not yet display the same dedicated, public cosmetic adverse-event infrastructure as mature pharmacovigilance systems. Cosmetic reactions are commonly managed by clinicians without product identifiers, retained samples, or notification to a cosmetic regulator. Consumers may complain through the National Consumer Helpline or platform grievance systems, but a commercial grievance is not automatically converted into a safety signal [25,49]. This produces under-ascertainment and loses the link between clinical harm and product enforcement.

A national reporting form should capture product name and images, batch, manufacturer, importer, RC or licence number, seller and platform, purchase date, use pattern, onset and outcome, concomitant products, medical assessment, laboratory findings, and whether a sample remains available. Serious events should be mandatory for manufacturers, importers, and responsible persons, with defined timelines. Clinicians, laboratories, consumers, and platforms should have simple voluntary routes. Reports should feed a signal-management process, not merely a complaint inbox.

8.3 Public alerts and recall effectiveness

An alert is effective only if it can be acted upon. Notices should use standardized fields, downloadable images, chemical results, legal status, affected batches, distribution channels, and instructions for consumers and sellers. Platforms should acknowledge receipt, identify matching and near-matching listings, freeze inventory, notify purchasers, preserve seller records, and report completion. State regulators should verify retail withdrawal through targeted checks. Recall effectiveness should be measured as the proportion of traceable units quarantined or consumers contacted, the time to delisting, recurrence of cloned listings, and detection in follow-up sampling.

9 International comparison

The Minamata Convention establishes the global control baseline for mercury-added skin-lightening cosmetics, historically using a 1 ppm threshold and subsequently strengthening controls on mercury-added cosmetics [50-52]. WHO and UNEP emphasize legislation, enforcement, customs training, laboratory capacity, awareness, and action across production and trade [1,27,50]. India's 1 ppm unintentional limit for non-eye cosmetics aligns with the key global threshold, but treaty compliance depends on preventing manufacture, import, and export—not only writing a concentration into domestic rules.

The European Union combines a pre-market responsible-person model, a cosmetic product notification portal, safety assessment, serious undesirable-effect reporting, and the Safety Gate rapid-alert system [53-56]. This does not eliminate illegal products, but it creates a common product identity and a cross-border feedback channel. The United States historically relied more heavily on post-market authority; the Modernization of Cosmetics Regulation Act of 2022 added facility registration, product listing, serious adverse-event reporting, records access, and mandatory recall authority, while FDA continues to warn and test mercury-containing skin products [28,29,57-60]. Canada uses a Cosmetic Notification Form and

publishes a hotlist of restricted ingredients [61,62]. These models show that notification or listing is useful only when coupled with an identifiable responsible party, adverse-event duties, inspection, and public enforcement data.

India should not copy any one system wholesale. A resource-sensitive model can use its existing import registration and State licensing data as the backbone of a verification service. The highest-value additions are public validation of product identity, mandatory platform checks, structured serious-event reporting, standardized rapid alerts, and a risk-based national sampling plan. These are information architecture reforms as much as legislative reforms.

Table 4. Comparison of selected regulatory systems

System	Pre-market identity	Adverse-event mechanism	Recall / alert feature	Lesson for India
India	Import registration; State manufacturing licence	No prominent unified public cosmetic vigilance portal	Voluntary recall plus statutory enforcement tools	Convert existing approvals into a verifiable, interoperable identity layer
European Union	Responsible person, product information file, CPNP notification	Serious undesirable-effect reporting	Safety Gate cross-border rapid alerts	Shared product identity and structured alert exchange
United States	Facility registration and product listing under MoCRA	Mandatory serious adverse-event reporting	FDA mandatory recall authority; public warnings	Link listing, records access, event reporting, and recall power
Canada	Cosmetic notification and ingredient hotlist	Consumer and industry incident reporting	Public advisories and compliance action	Simple notification can support prioritization if data are current
Minamata / WHO	Treaty control for mercury-added products	Public-health surveillance encouraged	International cooperation and capacity building	Integrate customs, laboratory, health, and market interventions

10 Why non-compliant products continue to reach consumers

The evidence supports a multi-causal explanation. First, the economic incentive is strong: mercury can create rapid perceived efficacy in a market shaped by colorism. Second, formal controls are consignment- and document-centered, whereas e-commerce is listing-centered and seller identities change quickly. Third, import registration information is not consistently exposed as a public, machine-readable verification layer. Fourth, central and state responsibilities fragment intelligence and laboratory results.

Fifth, surveillance samples are too sparse and are rarely selected using online risk signals. Sixth, many adverse reactions never reach regulators with an identifiable product. Seventh, voluntary recall presumes an accountable entity that unauthorized imports lack. Finally, enforcement often removes an item without disrupting the seller network, payment trail, inventory, and cloned listings.

These mechanisms interact. An unregistered cream can enter in a small parcel, be listed under a generic name, omit the importer and registration number, generate sales before sampling, and then be relisted after takedown. The absence of a complaint does not indicate safety because renal injury may be delayed or initially asymptomatic. Conversely, a positive screen without confirmatory testing or chain of custody may be insufficient for prosecution. A robust system must therefore connect identity verification, risk detection, analytical confirmation, clinical signals, and enforcement feedback.

11 Proposed risk-based framework for India

11.1 Establish verifiable product identity

CDSCO should publish an authoritative, searchable register of imported cosmetics and responsible Indian entities, with an application programming interface for platforms and customs. State licences and product categories should be linked where legally and technically feasible. Each record should include brand, product, variant, manufacturing site, responsible entity, validity status, and approved label images. A QR code may help consumers, but the security anchor must be the server-side record; printed codes alone can be copied.

11.2 Make platforms active control points

Before an imported cosmetic goes live, the platform should validate the registration number against the register and match brand, variant, manufacturer, and importer. Seller identity and an Indian service address should be verified. High-risk terms, images, and claims should trigger enhanced review. Platforms should preserve listing histories, invoices, fulfillment records, and seller linkages; prevent relisting by image and network matching; and provide regulators with a standardized notice-and-action channel. Duties should apply proportionately to social commerce and direct-to-consumer intermediaries as well as large marketplaces.

11.3 Build a national sampling and laboratory network

A central annual plan should set a minimum risk-based sample frame while allowing State additions. Priority scores should combine absent or invalid registration, foreign origin, skin-lightening or rapid-result claims, low price, prior alerts, seller churn, consumer complaints, and vulnerable-user targeting. XRF can support field triage if performance is verified for creams and packaging; accredited laboratories should confirm positives and a subset of negatives. Harmonized methods, decision rules, proficiency testing, and a shared laboratory information system are essential.

11.4 Close the safety-signal and recall loop

A cosmetic safety portal should accept consumer and clinician reports and allow upload of label photographs and invoices. Mandatory serious-event reporting should apply to manufacturers, importers, and responsible persons. Poison centers, nephrologists, dermatologists, and clinical laboratories should receive case definitions and referral guidance for suspected mercury exposure. When a signal is validated, the same structured record should trigger testing, platform takedown, customs watch-listing, State retail checks, purchaser notification, and public communication.

11.5 Use graduated but credible enforcement

Documentary defects with low immediate risk may justify correction and enhanced monitoring; absent authorization, falsified provenance, repeated relisting, obstruction, or extreme mercury should trigger rapid stop-sale, seizure, investigation, and prosecution. Enforcement outcomes should be published in a searchable format. Penalties must exceed the gains from rapid online sales, and repeat seller networks should be investigated across platforms. International alerts should be ingested into domestic screening even before local injury reports emerge.

Table 5. Proposed surveillance indicators

Domain	Indicator	Suggested performance measure
Market identity	Imported listings verified against COS-2 data	Proportion verified before publication; mismatch rate
Detection	High-risk listings or parcels screened	Coverage by risk stratum; time from signal to purchase
Laboratory	Confirmatory testing completed	Median turnaround; proficiency-test performance
Platform response	Listings and clones removed	Time to removal; 30/90-day relisting rate
Recall	Inventory and purchasers reached	Units quarantined; consumers notified; effectiveness-check completion
Health signals	Serious reports with identifiable product	Completeness, signal-validation time, regulatory actions initiated
Transparency	Structured alerts published	Time from confirmation to alert; reuse by States/platforms/customs

12 Research agenda

India needs a reproducible national market study with probability-informed sampling across formal retail, major marketplaces, social commerce, border regions, and informal markets. Studies should purchase products as consumers do, verify registration and authenticity, analyze multiple batches, and report all metals using validated methods and measurement uncertainty. Biomonitoring should be linked to detailed product histories and should include household co-exposure. Economic research should evaluate seller networks, price incentives, and the effect of platform controls. Implementation research should test whether registration verification, image matching, purchaser notification, and recall audits reduce recurrence.

Regulatory science should also clarify impurity limits by product category, especially for cadmium and sensitizing metals; develop reference materials for cream matrices; compare portable screening with confirmatory methods; and define decision thresholds that incorporate uncertainty. A public dataset of anonymized inspections, samples, results, alerts, and actions would allow independent evaluation. Without

denominator data—how many listings, consignments, and products were screened—enforcement counts cannot measure performance.

13 Conclusions

India has a recognizable legal pathway for cosmetic manufacture, import registration, standards, labeling, sampling, analysis, and recall. Yet hazardous skin-lightening products persist because the pathway is discontinuous at the points where contemporary commerce is most dynamic: small-parcel import, third-party marketplace listing, mutable seller identity, and post-sale signal detection. The resulting problem is not simply a missing mercury limit. It is a failure to maintain product identity and regulatory accountability from border or factory to consumer and back to enforcement.

The most effective response is a closed-loop surveillance system. Registration and licensing data should become publicly verifiable marketplace controls; online and border intelligence should determine sampling; screening should be confirmed by accredited quantitative methods; clinical and consumer reports should be structured as regulatory signals; and every validated signal should propagate rapidly to platforms, customs, States, laboratories, and consumers. This approach is more feasible and more protective than attempting universal pre-market testing. It concentrates resources where hazard, exposure, and evasion are most likely, while preserving proportional regulation for compliant industry.

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