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Reforming India's Pharmaceutical Regulation: Addressing Structural Gaps and Ensuring Drug Safety

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Abstract: ***India's pharmaceutical industry remains a global manufacturing powerhouse, yet recurrent episodes of substandard and contaminated medicines—culminating in recent paediatric cough syrup tragedies at home and abroad—have exposed critical regulatory weaknesses that threaten public health, export credibility, and diplomatic influence. This article synthesises evidence from national surveillance data, high-profile contamination incidents, and policy debates to map the structural causes of failure: fragmented central–state governance, chronic inspector and laboratory shortages, weak legal deterrents, opaque loan-license and contract-manufacturing practices, and lagging digital traceability. It examines the international fallout in export markets and soft-power costs, and evaluates recent reform efforts, including mandatory GMP alignment and the proposed Drugs, Medical Devices and Cosmetics Act, 2025. Drawing on comparative best practices, the paper proposes a nine-point reform agenda that prioritises centralised oversight, rapid independent batch testing for high-risk products, expansion and accreditation of laboratory capacity, stronger liability for brand owners using contract manufacturers, mandatory serialisation and real-time recalls, reinforced pharmacovigilance, and restored legal deterrence for deliberate or repeat offences. The article argues that decisive structural reform, technological adoption, and transparent enforcement are essential to restore trust, protect vulnerable populations, and secure India's long-term role in global pharmaceutical supply chains.***

Keywords: India's pharmaceutical regulation, Substandard and spurious medicines, Diethylene glycol contamination, Pharmacovigilance, Batch testing and laboratory capacity

1. Introduction

The Indian pharmaceutical sector stands as a central pillar of the global healthcare supply chain. With a market size projected to approach INR 26 trillion (approximately $310 billion) by 2030 and annual exports crossing $30 billion in 2025, India maintains its position as the "Pharmacy of the World," catering to at least one-fifth of global generic drug demand and over half the vaccine requirements of many developing countries[123]. This export-driven growth, cost-effective production, and an overwhelming focus on generic medicines have presented a compelling success narrative recognised by both resource-poor and affluent nations.

Yet, despite these achievements, a parallel crisis is eroding the sheen of India's pharmaceutical prowess—the proliferation of substandard and spurious drugs due to regulatory deficits. In recent years, repeated scandals involving fatal contamination of paediatric syrups and frequent failures in drug quality checks have starkly exposed weaknesses within India's regulatory apparatus. These failures resulted in tragic deaths (most recently, the 2025 Madhya Pradesh cough syrup tragedy) and fractured international trust, prompting suspensions, export barriers, and global alerts from entities such as the World Health Organisation (WHO)[4,5,6,7].

This article explores the roots and ramifications of India's regulatory weaknesses, documents major incidents that have shaken public and global faith, and offers a comprehensive analysis of how these faults reverberate across export markets, public health, and policy. Drawing from myriad recent examples and synthesising the latest policy debates and sectoral developments, the report concludes with evidence-based recommendations to reform regulatory oversight, strengthen drug safety, and restore India's leadership in responsible global pharmaceuticals.

2. Literature Survey

The literature survey synthesises three strands of scholarship and policy literature relevant to India's recurring problems with substandard and spurious medicines: empirical accounts of contamination incidents and surveillance data, analyses of regulatory structure and governance, and evaluations of technological and legal reform options.

- Empirical evidence on contamination incidents and surveillance trends, Recent investigative reports, WHO medical-product alerts, and government surveillance bulletins
- Regulatory structure and governance analyses: Legal and public-administration studies emphasise the fragmentation of India's drug-regulatory ecosystem between central and state authorities, chronic understaffing of inspectorates, variability in licensing practices, and weak enforcement pathways.
- Technology, surveillance, and market-based interventions: Technical and implementation literature evaluate track-and-trace systems, batch-level serialisation, laboratory network expansion, and third-party independent batch testing as means to improve supply-chain integrity.
- Synthesis and Gap Identification: Existing literature provides strong evidence on what is failing and several proven interventions, but gaps remain in integrated evaluations that link regulatory design with operational

capacity and market incentives. Few studies model the combined effect of centralised legal authority, mandatory independent batch testing, and serialisation on export market confidence and on ground-level detection rates. There is limited empirical work on how joint liability for brand owners and contract manufacturers affects compliance behaviour. This article addresses those gaps by aligning incident-based evidence, surveillance statistics, and policy proposals into a cohesive reform framework and operational methodology.

3. Problem Definition

- Core problem statement: India's pharmaceutical sector suffers from a systemic regulatory gap that permits persistent production and distribution of substandard and spurious medicines, producing recurring public-health tragedies, eroding export credibility, and undermining diplomatic influence. Key dimensions of the problem
- Governance fragmentation and accountability vacuum: Overlapping responsibilities between central and state regulators create inconsistent licensing, uneven inspection standards, and opportunities for license shopping.
- Operational capacity shortfalls: Widespread vacancies among drug inspectors, limited accredited laboratory capacity, and under-resourced pharmacovigilance systems reduce detection rates and delay corrective action.
- Supply-chain opacity and contract manufacturing complexity: Extensive use of loan-license and contract-manufacturing arrangements weakens traceability, dilutes responsibility, and complicates enforcement when contamination occurs.
- Weak legal deterrents and inconsistent recall mechanisms: Recent decriminalisation of certain first offences and the absence of a legally mandated, time-bound national recall framework reduce the immediacy and severity of sanctions.
- Consequences and risks: Persistent regulatory failures risk further domestic morbidity and mortality, growing export restrictions or pre-shipment testing mandates by importing countries, loss of market share to competitors, and long-term reputational damage that will be costly to reverse.

4. Methodology

The methodology integrates document-based synthesis, incident-driven case analysis, regulatory mapping, and an operational-policy design exercise. It triangulates publicly available surveillance data, regulatory texts, and representative case studies to generate evidence-based recommendations and an implementable reform pathway.

Document Synthesis and Data Compilation

- Collect and harmonise data from national surveillance bulletins, CDSCO monthly alerts, parliamentary committee reports, WHO medical-product alerts, and high-profile investigative reports.
- Extract quantitative indicators: number of NSQ samples, spurious detections, prosecutions, inspector vacancies, and export values for affected product categories.
- Produce descriptive trends and cross-tabulations by year, state, product type, and export destination.

Case Study Analysis

- Select representative incidents (domestic and export-linked) that exemplify failure modes such as raw-material adulteration, production-line contamination, and oversight failures in contract-manufacturing oversight.
- For each case, reconstruct the timeline of events, regulatory response, laboratory findings, legal outcomes, and international repercussions.

Regulatory and Governance Mapping

- Map statutory responsibilities, licensing pathways, enforcement authorities, and recall procedures across central and state instruments.
- Compare existing legal provisions with WHO-aligned definitions and international best practices to identify statutory gaps and contradiction points.

Policy Option Design and Feasibility Assessment

- Define candidate interventions across three domains: institutional reforms (centralisation of specific powers, inspectorate strengthening), technical measures (mandatory independent batch testing, serialisation), and legal-reform measures (joint liability, recall mandates).
- Assess each intervention for effectiveness, implementation complexity, cost implications for industry and government, and potential barriers (political, administrative, legal).

Operational Protocol Development

- Draft model operational protocols for prioritised reforms: centralised pre-release independent batch testing for paediatric liquids; a national digital batch record template; joint-liability contractual clause model for loan-license agreements; and a time-bound national recall procedure.
- Define roles, decision points, and data flows between CDSCO, accredited labs, state inspectorates, brand owners, and import-authority liaisons.

Limitations

- Reliance on publicly reported surveillance and investigative data may understate true incidence due to underreporting.
- Feasibility scoring depends on available secondary evidence and expert judgement rather than primary stakeholder interviews; further empirical validation would strengthen implementation planning.

5. Discussion

Recent Incidents: The Indian Cough Syrup Tragedies and Beyond

The 2025 Madhya Pradesh Cough Syrup Crisis

In September and October 2025, a devastating incident unfolded in Madhya Pradesh and neighbouring Rajasthan that would reignite questions over India's ability to regulate its domestic pharmaceutical sector[576]. At least 20 children, most under the age of five, died after consuming a cold syrup named "Coldrif," manufactured by Sresan Pharmaceuticals, a Tamil Nadu-based company[8,9,4]. Laboratory analysis confirmed the syrup was adulterated with 48.6% diethylene glycol (DEG), a lethal industrial solvent with a well-

documented history of causing acute renal failure and death when ingested[695].

Authorities banned the syrup, arrested the owner, sealed the facility, and ordered a recall of all affected stock [8,5,6]. The Drugs Controller General of India (DCGI) and Central Drugs Standard Control Organisation (CDSCO) launched criminal proceedings and issued fresh guidance for state-level inspectors to strictly adhere to batch-testing protocols for raw materials and finished pharmaceuticals[10].

Yet, the swiftness of regulatory reaction belied a persistent undercurrent: these events were not isolated aberrations, but an echo of past tragedies.

A Pattern of Repeated Poisonings

India's track record is stained by recurring episodes of DEG or ethylene glycol adulteration in medicinal syrups. Key incidents include:

- **Gambia (2022):** Over 70 children died after ingesting cough syrups exported by Maiden Pharmaceuticals, Haryana, found to contain toxic levels of ethylene glycol and DEG. Despite a global alert from WHO and a media outcry, enforcement actions were slow and piecemeal][7,11,12,13].
- **Uzbekistan (2022-2023):** Eighteen child deaths and dozens of poisonings linked to Dok-1 Max, a syrup manufactured by India's Marion Biotech and contaminated in a similar fashion [14,7].
- **Jammu & Kashmir, India (2019-2020):** At least 12 children died due to consumption of tainted cold syrup with high DEG content.
- **Earlier Incidents:** Fatalities due to DEG-laced medicines were reported as far back as Mumbai in 1986 and New Delhi in 1998, [7,12].

Beyond syrups, the spectrum of substandard and counterfeit drugs in India has encompassed painkillers, antibiotics, anti-cancer medications, and even the reversal of legitimate factory labels to pass off spurious pills in state hospitals and the market.

Chronic Quality Failures in Routine Surveillance

Routine surveillance and testing have repeatedly flagged widespread non-compliance:

- In fiscal year 2024–25, 3,104 drug samples were found not of standard quality, while 245 were spurious or adulterated, out of 116,323 drug samples tested nationwide—a consistent 2–4% failure rate [15,16].
- Prosecutions for spurious and adulterated drugs rose to 961 in 2024–25, a nearly seven-fold increase over 2014–15 figures [16].
- Monthly CDSCO alerts routinely list dozens to over a hundred batches as "Not of Standard Quality (NSQ)" as well as spurious drugs, highlighting the persistent risks in the market [17,18].

Table 1: Major Incidents Involving Spurious Drugs and Their Consequences

Year	Location	Product(s)/Manufacturer	Contaminant/Issue	Deaths/Consequences	Regulatory Action
2025	Madhya Pradesh, India	Coldrif/Sresan Pharma	Diethylene glycol	20+ child deaths	Nationwide ban, factory sealed, arrest, recall
2025	Rajasthan, India	Dextromethorphan syrup/Kayson Pharma	Suspected contamination	3 child deaths	Distribution halted, investigation
2025	Gujarat, India	Respifresh TR, ReLife	Diethylene glycol	0 (detected early)	Halted production, recall, testing
2023	Telangana, India	Astrica Healthcare (anti-cancer drugs)	Spurious drugs	—	INR 4.35 crore seizure, criminal cases
2022	The Gambia	Maiden Pharma (various syrups)	Ethylene glycol/DEG	70+ child deaths	WHO alert, export ban, plant license revoked
2022	Uzbekistan	Marion Biotech (Dok-1 Max)	Ethylene glycol/DEG	18 child deaths	License suspended, facility shut, probe
2020	Jammu & Kashmir, India	Coldbest-PC (local manufacturer)	Diethylene glycol	12 infant deaths	Drug withdrawal, manufacturing halted
2006	Global	Various (India as the main source)	Spurious medicines	—	WHO: India is responsible for 54% global fake drugs
1998–1986	Various (India)	Various	Diethylene glycol	Dozens of deaths (cough syrups)	Factory closures, legal inquiries

These incidents, spanning both domestic and export markets, reveal a disturbing persistence of the same regulatory faults: poor quality control, inadequate batch testing, lack of oversight or transparency, and slow enforcement actions.

Global Impact: Erosion of Reputation and Export Dynamics

Deteriorating International Trust

The rash of contamination scandals involving exported Indian medicines, especially paediatric syrups, has battered India's global image. WHO product alerts from 2022 through 2025 cited Indian-made products as the source of child fatalities in The Gambia, Uzbekistan, and Cameroon, drawing intense scrutiny from importing nations and international health bodies [6,7,14,11,12].

African and Central Asian countries, traditionally relying on affordable imports from India for their public health programs, have begun to diversify their import baskets, exploring suppliers from China, Brazil, and Europe. Regulatory agencies in major markets such as the United States and Europe have intensified their inspections of Indian facilities and imposed stricter requirements for imported batches. The U.S. FDA, for instance, increased its audit

frequency and is considering tariff measures in the wake of these incidents [12].

Trade statistics illustrate both the magnitude and the fragility of India's export dominance:

- In FY-2025, Indian pharma exports grew 9.3% to $30.5 billion, with the U.S. accounting for over 32% of this volume [21].
- India provides 20–26% of Africa's generic pharmaceuticals and over one-third of the global demand for generics [13].

But continual safety concerns place this export status at risk, as exemplified by Gambia's new policy mandating pre-shipment quality testing for all Indian pharmaceuticals and increased U.S. tariff threats [4,23].

Soft Power and Diplomatic Setbacks

India's aspiration to be a healthcare leader for the Global South—catalysed by its vaccine diplomacy and record of affordable ARVs for HIV/AIDS—has been checked by repeated regulatory lapses[419]. Countries that once looked to Indian firms for pan-African or pan-Asian procurement have begun to question the reliability and safety of these products. Each new incident, especially those involving vulnerable populations like young children, erodes diplomatic capital, and it narrows down the window for Indian firms to rebuild trust.

A prominent example: after the 2022 Gambia scandal, WHO global alerts triggered not only recalls but also a re-evaluation of procurement policies by numerous low-income countries [7,11 13]. The resulting dip in confidence forced Indian exporters to redouble efforts in compliance with key markets.

Economic and Commercial Consequences

Quality alerts and international recalls not only undercut India's pharmaceutical exports but also:

- Forced to adopt enhanced oversight measures or lose access to lucrative regulated markets [13].
- Result in delayed new product approvals, loss of market share, or outright bans on specific manufacturers (as happened to Maiden Pharmaceuticals and Marion Biotech after Gambia and Uzbekistan deaths)[7,11,12,14].
- Diminish goodwill and negotiation leverage in setting new trade agreements, especially as competing nations tout their regulatory reforms [19].

Regulatory Challenges: Fragmentation, Understaffing, and Incomplete Oversight

The Structure and Gaps of India's Drug Regulation

India's pharmaceutical regulatory framework is administratively complex, with responsibility divided between the national Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health and Family Welfare and 28 states and 9 union territories, each with its own Drug Control Organisation or authority [20,21,22]. On paper, CDSCO is responsible for drug standards, import quality, new drug approvals, and coordination, while state authorities handle licensing of manufacturing, retail, and enforcement in their jurisdictions.

However, this division breeds fragmentation and confusion:

- **Licensing inconsistencies:** States often issue licenses for products or fixed-dose combinations not approved by CDSCO, enabling the legal manufacture of potentially irrational and unsafe medicines.
- **Oversight gaps:** Many states lack adequate resources (in both personnel and laboratory capacity) to conduct routine or risk-based inspections, allowing manufacturers to shop for the least stringent region ("license shopping") [9,23].
- **Patchy enforcement:** Coordination between central and state regulators is often weak, with states frequently defaulting to the centre for problem-solving but lacking robust joint action plans or uniform enforcement of bans, recalls, or penalties [5].

Chronic Understaffing and Inspection Deficiencies

Staff and resource shortages weaken enforcement. As of late 2024, out of 504 sanctioned posts for drug inspectors under CDSCO, over 300 (about 60%) remained vacant[23,24,25]. State regulatory authorities fare no better in inspector numbers or laboratory capacity. Several parliamentary committees and sectoral reports have called this shortage a major roadblock to systematic, comprehensive drug safety enforcement.

Further, laboratory infrastructure to test drug samples is stretched thin, with frequent delays, inadequate random-batch sampling, and limited staff training [26]. Even large states often lack sufficient, accredited drug labs; the capacity to test for excipient contaminants such as DEG on every batch is rare.

Inadequate Surveillance and Unreliable Data

India's pharmacovigilance system, though improved in recent years, remains under-resourced and poorly integrated. Problems include:

- **Underreporting**: Adverse drug reaction (ADR) reporting is voluntary and much lower than global benchmarks, especially in rural areas or among non-specialist providers[2728].
- **Inconsistent terminology**: The term "counterfeit" or "falsified" is absent in the Drugs and Cosmetics Act, complicating legal action and harmonisation with WHO definitions.
- **Data gaps**: Several states fail to submit regular updates on NSQ drugs, leaving the national quality picture incomplete[18].

Weaknesses in Legal Deterrence and Recalls

Although the Drugs and Cosmetics Act prescribes harsh penalties for fake or NSQ drugs, prosecutions are rarely completed, with most enforcement actions limited to warnings, temporary suspension, or modest fines. Moreover, India still lacks a robust, legally mandated drug recall mechanism at the national level; most recalls occur after deaths or major alerts, rather than as preventive action[19].

The Jan Vishwas (Amendment of Provisions) Act 2023, which decriminalised the first offence of manufacturing or distributing substandard or adulterated drugs by replacing jail time with monetary penalties, further diluted deterrence, according to many health experts and advocates [4].

Issues in Contract Manufacturing and Loan Licensing

A vast portion of drug production in India is handled by third-party contract manufacturers under "loan license" provisions, used especially by marketing companies or new entrants who lack their own facilities [29,30,31,32]. While this model accelerates domestic output and exports, it poses complex regulatory challenges:

- **Oversight dilution:** Quality compliance is harder to enforce when the "brand owner" is divorced from the production process, and both parties may blame one another in case of violations or contamination.
- **Traceability challenges:** Loan licensees often lack the resources and expertise to conduct comprehensive supplier audits or in-process quality checks, increasing the risk of subpar outputs entering the legal market.

Inadequate Technology Use and Digitalisation

India lags in the large-scale deployment of digital tools such as track-and-trace systems, robust QR/barcode-based serialisation, or supply-chain transparency platforms that have become standard in regulated Western markets [22,33]. This technological deficit hinders the timely detection of substandard or counterfeit drugs, undermines recall efforts, and makes it difficult to assure global importers of product authenticity.

Policy Landscape: Recent Reforms and Legislation

The Upcoming Drugs, Medical Devices and Cosmetics Act, 2025

In direct response to the recent tragedies and chronic regulatory shortcomings, the Indian government is preparing to replace the archaic Drugs and Cosmetics Act of 1940 with the comprehensive Drugs, Medical Devices and Cosmetics Act, 2025 [34,35].

Key features expected in the new law include:

- **Empowerment of CDSCO:** For the first time, CDSCO will receive statutory authority to take swift penal and remedial action, including immediate suspension or shutdown of manufacturers linked to fake, substandard, or contaminated drugs[34].
- **Digitisation and Transparency:** The law proposes digitisation of the licensing process, centralisation of databases, and improved coordination between central and state regulators to enable real-time action and supply-chain visibility [35].
- **Enhanced Testing and Surveillance:** The Act seeks to upgrade laboratory infrastructure, mandate stringent batch-testing (especially for high-risk exports), and enforce regular compliance auditing[34].
- **Stricter Penalties and Product Recalls:** Provisions for faster recall mechanisms, higher penalties for non-compliance, and greater accountability for both manufacturers and marketing/license-holders are included [34].

The draft bill is slated for introduction in Parliament and is a direct response to both domestic demands and global regulatory pressure.

Mandatory Good Manufacturing Practices (GMP) and Global Benchmarking

Since October 2023, Indian authorities have required all pharmaceutical manufacturers to implement GMP (Good Manufacturing Practices) standards articulated by global agencies, giving six months for compliance by large firms and an extended time for MSMEs[33]. This move is expected to narrow the quality compliance gap between products intended for regulated export markets (like the US and EU) and those distributed domestically or in less regulated import environments.

Routine Drug Quality Alerts and Increased Inspections

CDSCO now publishes monthly lists of drugs deemed "Not of Standard Quality" or spurious, and has implemented risk-based, as well as random, inspections of manufacturing, warehousing, and distribution units[17]. Between December 2022 and September 2025, over 900 manufacturing and testing units were inspected, resulting in regulatory actions—including license suspensions or revocations—in nearly 700 instances [15].

Strengthening Pharmacovigilance and Post-Market Surveillance

The government is expanding the Pharmacovigilance Programme of India (PvPI), increasing the number of Adverse Drug Reaction Monitoring Centres, and exploring the integration of digital platforms to encourage reporting by clinicians and consumers alike [27,28].

6. Results & Discussion

Evidence-Based Policy Recommendations

Drawing from recent tragedies, expert analyses, and lessons from comparable global regulatory regimes, the following recommendations are critical for India to regain its standing and ensure drug safety both domestically and internationally.

1) Centralize and Harmonize Regulatory Oversight

- **Establish a Unified Drug Authority:** Temporarily strip state regulators of the power to grant manufacturing licenses for export without central clearance. Only empower those with audited labs and staff to perform licensing functions.
- **Mandate cross-state and random inspections:** Staff drug inspector teams drawn both from CDSCO and a rotating pool of state officers for periodic audits and cross-inspections, preventing regulatory "capture" at the state level.

2) Address Resource Gaps and Upgrade Laboratory Infrastructure

- **Fill inspector vacancies and boost budgets:** Implement a time-bound plan to fill all sanctioned inspector posts at both central and state levels, and prioritise budget allocations for training, salary parity, and laboratory upgrades.
- **Expand and accredit laboratories:** Build new NABL-accredited laboratories in high-output states and major pharma clusters and equip them with technology for rapid excipient testing.

3) **Mandate Comprehensive Batch Testing for High-Risk Drugs**
- **Independent batch testing for raw materials and finished products:** Mandate third-party, centrally registered testing for all paediatric liquid medicines and high-risk injectable batches before market release.
- **Create traceable digital records:** Each batch must have a digital record from raw material procurement to finished product dispatch, ensuring supply-chain traceability and fast recalls if needed.

4) **Restrict and Audit Contract Manufacturing and Loan Licensing**
- **Stricter scrutiny for contract manufacturers:** Make brand owners jointly liable for any safety violations at outsourced facilities, with penalties, blacklisting, and public disclosure for violators.
- **Regular audits of loan license arrangements:** Establish a formal register of all third-party manufacturers, require public disclosure of compliance records, and conduct surprise audits.

5) **Strengthen Pharmacovigilance and Community Reporting**
- **Digitise and publicise adverse event data:** Develop a user-friendly mobile app for ADR reporting, linked to a public dashboard showing action taken.
- **Engage private healthcare and pharmacists:** Require routine ADR reporting and self-audits from private hospitals, pharmacy chains, and e-pharmacies; incentivise compliance with tax breaks or penalties.

6) **Adopt and Enforce Modern Technologies**
- **Serialisation and blockchain:** Implement QR code-based serialisation or blockchain-driven track-and-trace for all prescription medicines, prioritising high-risk categories and exports.
- **Rapid notification and recall:** Establish a centralised, real-time national recall system, with legal compulsion for immediate public disclosure.

7) **Enhance International and Cross-Border Cooperation**
- **Harmonise export standards:** Mandate that drugs destined for Africa, Southeast Asia, or any country without robust regulatory systems meet the same standards as those supplied to the U.S. or EU.
- **Build international verification databases:** Participate in WHO-led global data-sharing on drug quality, enabling importing nations to check compliance and alert for unsafe shipments.

8) **Revisit and Reform Legal Frameworks**
- **Restore strong deterrent penalties:** Reverse recent decriminalisation of substandard drug manufacture/distribution for first-time offenders. Make deliberate adulteration or repeat-offending a non-bailable, serious crime.
- **Define and criminalise "counterfeit" medicines:** Align Indian law with WHO definitions to enable prosecutions and harmonise enforcement.

9) **Foster Transparency and Public Accountability**
- **Publish compliance data proactively:** Require CDSCO and all state bodies to publish inspection, audit, prosecution, and recall data on their websites within days of action, restoring public confidence.
- **Protect and incentivise whistle-blowers:** Institute legal protections and financial rewards for whistle-blowers from within pharma companies, following models that succeeded in the Ranbaxy scandal[36].

7. Conclusion

India's pharmaceutical sector, justly celebrated for its immense contributions to public health and affordable medicines worldwide, is at a regulatory crossroads. The deaths of children in Madhya Pradesh, The Gambia, Uzbekistan, and elsewhere are not mere statistical aberrations—they are clarion calls for structural reform and renewed vigilance.

The sector's dual realities—of world-class export capability and tragic oversight failures—can no longer co-exist unchallenged. If India is to sustain and expand its place as the Pharmacy of the World, it must urgently build a regulatory system worthy of that title: centralised, transparent, resourced, technologically modern, globally harmonised, and uncompromising on safety.

Structural changes, tough enforcement, technological innovation, and the political will to see every life as equally deserving of safe medicines are not only moral imperatives; they are existential requirements for the survival and legitimacy of India's pharmaceutical future. The coming years and reforms—starting with the Drugs, Medical Devices and Cosmetics Act, 2025—represent pivotal reforms

The deaths of infants from "poison in a bottle" must never be repeated. The time to act, and to lead by the highest standards, is now.

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