International Journal of Environmental Sciences
ISSN: 2229-7359
Vol. 11 No. 20s, 2025
https://theaspd.com/index.php

Counterfeit Medicines And Genuine Harm: An Inquiry Into The Silent Ecological Crisis In India

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Abstract
The environmental consequences of the counterfeit medicines have largely remained peripheral in India's policy debates, largely suppressed by concerns around patient safety and drug efficacy. Yet, the harm they cause goes beyond the clinics, it seeps into water bodies, soils, and ecosystems. India, where pharmaceutical production is vast and regulatory enforcement is uneven, the challenge is even more complex.
This study explores the ecological fall-out of unregulated counterfeit drug production, and evaluates how India's legal framework handles this dual crisis, which is ***public*** *and* ***environmental****. While laws exists, like the Drugs and Cosmetics Act (1940), the Environment (Protection) Act (1986), and the Waste Management Rules (2016), their enforcement remains scattered and sometimes null. Agencies like the CDSCO focus on drug safety but not the waste, while Pollution Control Boards often overlook pharmaceutical counterfeiting altogether, creating a blind spots where environmental damage goes blatantly unchecked.*
The study also mainly calls for rethinking, although not discarding, the existing structure - by integrating environmental oversights into pharma governance. It proposes a stronger coordination between the drugs and environmental regulators, extending ***Extended Producer Responsibility (EPR)*** *to pharma, and improving the public systems for proper medicine disposal. It also emphasises the urgent need for targeted research on the environmental toxicity of counterfeit APIs (where the research gap intensifies). Ultimately, the paper argues that public health extends beyond the human body- it includes the environment that sustains us.*
Keywords: *Counterfeit medicines, ecological impact, pharmaceutical regulation, policy reforms, environment toxicology.*

1.INTRODUCTION

The spread of counterfeit medicines isn't really a new issue, but it's one that has evolved, becoming more dangerous and, in some ways, more difficult to contain. It's not just about people being sold ineffective pills or mislabeled packaging.[1] The problem now extends well beyond that. In India, particularly, the situation has grown more tangled-almost unmanageably so, due to a convergence of several factors such as high demand for pharmaceuticals, persistent gaps in regulatory enforcement, and the sheer scale of both legitimate as well as illegitimate drug production.[2] It's not such of a straightforward story as it prima facie seems to be. Counterfeit medicines are typically produced in off-grid, unregulated facilities, often with no safety checks, no quality control, and, unsurprisingly, no environmental protocols as well.[3] Toxic solvents, sub-standard ingredients, and chemical by-products end up dumped into water sources, drained into fields, or burned in the open. The impact is often slow, cumulative, and not immediately visible - until it is. Some rivers become toxic, leading to the aquatic life, especially fish, shows signs of hormonal disruption. And antibiotic residues - trickling in trace amounts through water, start to shape microbial resistance patterns that eventually circle back to humans. These aren't a set of isolated events, but often are part of a pattern. One that we're only beginning to understand, let alone regulate.
It's a strange and troubling irony, considering that India is recognized globally as one of the leading producers of pharmaceuticals. By volume, it's the third largest in the world.[4] But that very distinction comes with a darker shadow. Alongside the booming legitimate industry, there exists an underbelly, one filled with

substandard, falsified, and flat-out fake medicines available all across the nation.[5] These **SSFFC** (substandard, spurious, falsely labelled, falsified and counterfeit) products aren't just undermining public trust in healthcare systems, they're actively contributing to rising illness, avoidable deaths, and something that gets talked about far less: environmental damage. Even though India has a web of agencies and laws theoretically designed to prevent this kind of thing,[6] enforcement often falls far short of what's needed. There are cracks in the system, some small, some massive, and through these, counterfeiters have carved out entire markets.

The World Health Organization (hereinafter referred as **WHO**) estimates that roughly one in ten medical products in low- and middle-income countries is either substandard or falsified.[7] That's not a small number. Within India itself, estimates suggest that about 8 to 10 percent of the drugs being sold don't meet basic quality standards or are outright fake.[8] These aren't mild deviations either, many contain incorrect dosages, wrong or harmful ingredients, or sometimes no active compound at all. The results? Well, they're quite grim, often leading to treatment failures. The spread of drug-resistant infections is at peak, and yes, people dying from those medicines that were supposed to help them.[9]

The problem is particularly acute in rural and semi-urban regions. There, regulatory reach is limited, sometimes nearly absent. Public awareness is also lower in these areas, making communities more vulnerable.[10] Added to this is the fact that making counterfeit drugs is highly profitable, while also relatively easy to get into, and it's not hard to see why the problem continues to escalate. Law enforcement is stretched thin, and punishments (when they do occur) are rarely severe enough to deter large-scale operations.

Coordination between agencies can often be seen to be a mess. The Central Drugs Standard Control Organization (CDSCO), state-level drug controllers, customs departments, and local police all have some piece of the puzzle, but they don't always fit those pieces together.[11] Everyone seems to be operating in parallel, rarely in sync. The Drugs and Cosmetics Act of 1940 does exist to provide regulatory guidance, but its implementation varies wildly from one state to another. Drug inspectors—many of whom are overworked and poorly equipped—struggle just to keep up. Investigating offenders, collecting samples, preparing legal cases… it's too much for too few people. And even when action is taken, penalties tend to be light. Offenders—especially those behind the bigger networks—often walk away with fines or short-term legal consequences. It sends the wrong message: that this kind of crime isn't all that serious, when in fact, it absolutely is.

Then there's the digital dimension. Online sales have opened up new frontiers for the counterfeit drug trade. E-pharmacies, many unregulated or only loosely monitored, offer fake medicines with little oversight.[12] This has made it harder for traditional regulators to intercept illicit transactions. The government has made some attempts—like introducing draft rules for online pharmaceutical sales and launching digital monitoring programs—but enforcement remains uneven. It often feels reactive, like the system is always playing catch-up.

Cross-border networks only complicate things further. Many of the operations that produce or distribute counterfeit drugs aren't confined to national borders. They involve smuggling, organized crime, and informal markets that stretch across countries. Intelligence-sharing in these cases is minimal, and India's involvement in international enforcement cooperation is still, by most accounts, fairly limited.

Political will, too, seems to come and go. There are moments of outrage, periodic raids, and announcements of reform. But sustained investment—in training, infrastructure, regulatory reform—is lacking. There's a kind of inertia that sets in. And it doesn't help that the problem is still viewed narrowly as a public health issue, when in fact, it's intertwined with larger socio-economic and environmental dynamics. Environmental concerns, in particular, have been given far too little attention. And that's becoming increasingly dangerous.

Counterfeit drug manufacturing doesn't follow any of the rules that apply to licensed pharmaceutical companies. It happens off the grid—unregistered facilities, often hidden in rural or newly formed urban areas,

far from regulatory oversight. These setups don't seek or receive environmental clearances. There's no monitoring, no recordkeeping, no accountability.[13]

What does this mean in practice? It means chemical solvents, active pharmaceutical ingredients (APIs), and toxic by-products are dumped into rivers, drains, or nearby fields without a second thought. Burning is common too—often done in the open, with no pollution control. In short, counterfeit drug operations are polluting the environment in ways that are both continuous and largely invisible to the authorities.[14]

And it's not just about one-off incidents. These pollutants—antibiotics, hormones, painkillers—persist in the environment. They make their way into the water table. They accumulate in soil. They affect wildlife. Studies have linked pharmaceutical pollution to antimicrobial resistance in waterborne bacteria, hormonal imbalances in aquatic life, and broader ecosystem disruption. These aren't abstract risks—they're unfolding now. Licensed pharmaceutical companies, even with all their flaws, are at least subject to environmental controls. They're expected to conduct Environmental Impact Assessments, comply with Zero Liquid Discharge (ZLD) mandates, and install pollution control equipment. Counterfeiters do none of this. They operate with complete impunity. Another issue, one that's often overlooked, is what happens to counterfeit drugs that are seized. There's no national system for the disposal of such pharmaceuticals. Often, they're stored indefinitely in poorly managed warehouses or burned in open air. Sometimes, they're just dumped. The result? Toxic leaks, chemical spills, and in some cases, accidental exposure to dangerous substances. Neither the Central Pollution Control Board nor most State Boards have clear, standardized guidelines for dealing with this type of pharmaceutical waste.[15]

All of this is made worse by the fact that drug enforcement agencies and environmental regulators barely interact. They operate in separate silos. One focuses on the drug market; the other handles pollution control. There's no integrated approach—no shared database, no routine collaboration, not even common terminology in many cases. And because of that, environmental harm caused by counterfeit medicine production often goes unnoticed, unreported, and, of course, unpunished.

In India, this failure is especially troubling. The country's sheer population density, its dependence on groundwater, and its already stressed urban and rural ecosystems make it acutely vulnerable. Some of the regions hardest hit by pollution—Uttar Pradesh, Bihar, Andhra Pradesh—are also where counterfeit pharmaceutical activity tends to cluster. It's a dangerous overlap, and one that could easily tip into local ecological crises if left unaddressed.

What's needed now is more than just stricter laws. It's a mindset shift. Counterfeit drug manufacturing must be treated not just as a crime or a public health risk, but as an environmental hazard. Environmental audits should become part of post-seizure protocols. A national pharmaceutical waste tracking system is overdue. Regulators—both environmental and pharmaceutical—need shared platforms and joint training programs. Forensic labs should be equipped to detect pharmaceutical pollutants. And perhaps most importantly, public health and environmental protection must stop being seen as separate domains. They are deeply connected.[16]

1. Policy And Legislative Gaps In Addressing Environmental Impacts Of Counterfeit Medicines In India

The rise of counterfeit medicines in India isn't just a health crisis anymore—it's increasingly becoming an environmental one, too. And yet, when we look at the country's legal and policy frameworks, it's clear there's no real structure in place to deal with the ecological fallout from these illicit operations.[17] While India has made progress in drug regulation and also has several environmental protection laws on the books, the overlap—the space where pharmaceutical crime causes environmental harm—is mostly neglected. This lack of recognition has created a dangerous kind of legal blind spot, one that has gone largely unnoticed by policymakers and regulators alike.

Let's start with the basics. The main legislation that governs drug safety and quality in India is the **Drugs and Cosmetics Act, 1940**. It's a foundational piece of legislation, no doubt, and it outlines how drugs should be

manufactured, sold, distributed, and monitored. It criminalizes fake and adulterated medicines and grants power to regulatory authorities to inspect and take action. But here's the thing: this Act is entirely centered around human health outcomes. It talks about protecting patients and ensuring medicine quality, but it makes no mention—none at all—of environmental consequences. There's no legal requirement to investigate whether illegal drug production has damaged nearby water bodies, contaminated air, or polluted soil. Drug enforcement actions and environmental concerns live in separate worlds, legally speaking.[18]

In order to substantiate the above claim, the authors would draw your attention to the drug alert issued by CDSCO in the months of January, 2025 reproduced below.[19]

Image 1

Drug Alert for the Month of January–2025 (Revised)

List of Drugs, Medical Devices, Vaccine and Cosmetics declared as Not of Standard Quality/Spurious/Adulterated/Misbranded for the Month of January– 2025 (Revised)

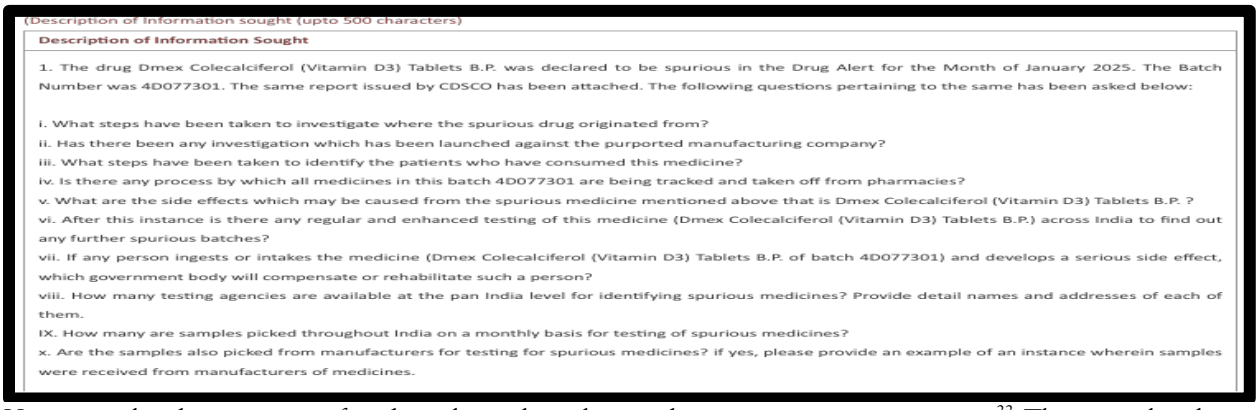
S.No.	Name of Drugs/medical device/cosmetics	Batch No.	Date of Manufacture	Date of Expiry	Manufactured By	Reason for failure	Drawn By	Firm's reply	Remarks
23.	Dmex Colecalciferol (Vitamin D3) Tablets B.P.	4D077301	09/2023	08/2026	M/s Aeron Lifesciences Pvt Ltd, Kathwada, Ahmedabad as per the Investigation Report	Assay of Cholecalciferol	Drugs Inspector, Ahmedabad Zone	The actual manufacturer (as per label claim) has informed that the impugned batch of the product has not been manufactured by them and that it is a spurious drug.	As per the Investigation report the product is purported to be Spurious.

the basis of random testing about a common drug known as **Colecalciferol** (Vitamin D3) tablets manufactured by a particular company to be spurious in nature. The above notification may easily be accessed on the CDSCO portal. However, the environmental impact of such chemicals being used to produce spurious drugs have not been investigated into by the governmental departments. This is plainly because of a lack of coordination between the central drug watchdog and the environmental regulators in the country. While the unregulated use of chemicals for manufacture of such drugs may lead to extremely deleterious ecological impacts as noted across the world, we suffer from legislative inertia and governmental neglect in ensuring a suitable and effective legislative model in this respect. There have been countless such spurious medicines which have been flagged by CDSCO in this year alone.[20]

One RTI application was also filed by the authors, with respect to the kind of investigation launched by the nodal authorities into the manufacture of the above drugs.[21] The RTI application was filed on 24/05/2025 to gain an insight into the remedies undertaken by the authorities to investigate the source of production of counterfeit medicines. It expected an answer as to the mechanism which currently exists in India to deal with such situations keeping in view the far-reaching environmental impacts that unregulated waste management at such manufacturing units may produce.

The questions have been reproduced below:

Image 2



(Description of Information sought (upto 500 characters)

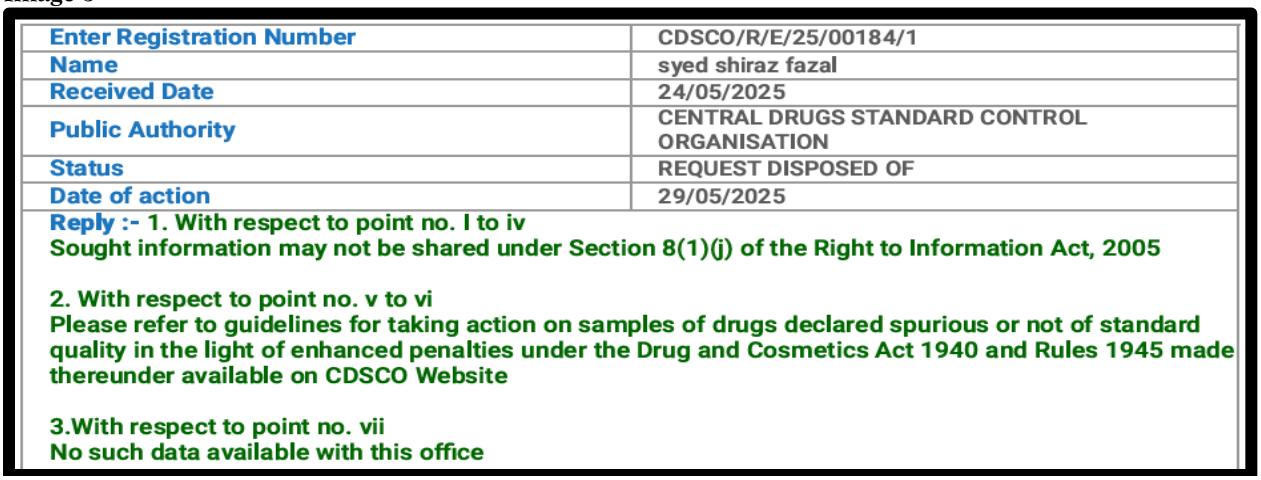
Description of Information Sought

1. The drug Dmex Colecalciferol (Vitamin D3) Tablets B.P. was declared to be spurious in the Drug Alert for the Month of January 2025. The Batch Number was 4D077301. The same report issued by CDSCO has been attached. The following questions pertaining to the same has been asked below:

i. What steps have been taken to investigate where the spurious drug originated from?
ii. Has there been any investigation which has been launched against the purported manufacturing company?
iii. What steps have been taken to identify the patients who have consumed this medicine?
iv. Is there any process by which all medicines in this batch 4D077301 are being tracked and taken off from pharmacies?
v. What are the side effects which may be caused from the spurious medicine mentioned above that is Dmex Colecalciferol (Vitamin D3) Tablets B.P. ?
vi. After this instance is there any regular and enhanced testing of this medicine (Dmex Colecalciferol (Vitamin D3) Tablets B.P.) across India to find out any further spurious batches?
vii. If any person ingests or intakes the medicine (Dmex Colecalciferol (Vitamin D3) Tablets B.P. of batch 4D077301) and develops a serious side effect, which government body will compensate or rehabilitate such a person?
viii. How many testing agencies are available at the pan India level for identifying spurious medicines? Provide detail names and addresses of each of them.
IX. How many are samples picked throughout India on a monthly basis for testing of spurious medicines?
x. Are the samples also picked from manufacturers for testing for spurious medicines? if yes, please provide an example of an instance wherein samples were received from manufacturers of medicines.

However, the department refused to share the relevant data citing privacy concerns.[22] The same has been reproduced below.

Image 3



Enter Registration Number	CDSCO/R/E/25/00184/1
Name	syed shiraz fazal
Received Date	24/05/2025
Public Authority	CENTRAL DRUGS STANDARD CONTROL ORGANISATION
Status	REQUEST DISPOSED OF
Date of action	29/05/2025

Reply :- 1. With respect to point no. I to iv
Sought information may not be shared under Section 8(1)(j) of the Right to Information Act, 2005

2. With respect to point no. v to vi
Please refer to guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Drug and Cosmetics Act 1940 and Rules 1945 made thereunder available on CDSCO Website

3.With respect to point no. vii
No such data available with this office

As may be noted from the above images, the department refused to answer questions from point no. I to IV (Image 2). This attitude speaks volumes about the callousness and opaque processes regulating the contemporary challenges around the issue. Thus, under the existing legal strictures it remains almost impossible to understand and remedy the nature of environmental harm caused due to toxins released by the manufacturing processes of spurious medicines in India. Such practices are not monitored in a serious manner by the governmental authorities. Currently, an appeal is pending with the department for the release of the relevant information.

The same pattern holds true when we look at India's environmental laws. Important frameworks like the **Environment (Protection) Act of 1986**, the **Air Act (1981)**, and the **Water Act (1974)** do provide tools to monitor pollution and hold industries accountable. But again, there's a catch. These laws apply to recognized, registered industries—companies that have licenses, listed addresses, formal compliance obligations. Counterfeit pharmaceutical units don't exist in these databases.[23] They operate illegally, usually under the radar, and don't apply for environmental clearances or pollution permits. As a result, they're rarely, if ever, inspected or penalized under environmental laws. That means they can dump waste, burn toxic materials, or release untreated effluents without anyone showing up to stop them. It's a loophole which is extremely wide, and yet it remains largely unaddressed.[24]

Even India's waste management laws, while quite detailed on paper, fail to catch the specific threats posed by fake drugs. The **Biomedical Waste Management Rules (2016)** and the **Hazardous Waste Rules (also 2016)** outline how hospitals, labs, and pharma manufacturers should handle biomedical and chemical waste. But

they assume that all waste comes from legitimate, trackable operations. Counterfeit manufacturers don't fit that mold—they produce waste in untraceable, informal, and unregulated ways. There's simply no clause that accounts for what happens when chemical sludge or discarded pills come from places that aren't officially supposed to exist. Enforcement in smaller cities or semi-urban industrial zones—where many of these illegal pharma units tend to operate—is already weak. So even if waste laws theoretically applied to counterfeiters (which they don't), it's unlikely they'd be meaningfully enforced at the local level. Most local pollution control boards are stretched thin as it is.[25]

Another overlooked area is **what happens after a raid**—when authorities seize a large quantity of counterfeit drugs. Ideally, there should be some protocol for how these substances are stored and destroyed. But in reality, they're often kept in police storerooms for weeks or months and later burned in the open or dumped into shallow landfills.[26] These methods, while convenient, can be extremely harmful. Burning pharmaceuticals, especially in uncontrolled environments, releases toxic fumes and particles. Dumping them into landfills allows chemicals to seep into the groundwater. And yet, there's no requirement for drug regulators to coordinate with the **Central Pollution Control Board (CPCB)** or **State Pollution Control Boards (SPCBs)** when disposing of seized medicines. It's all handled in isolation, without environmental agencies being looped in.[27]

There's no official standard operating procedure (SOP) that even mentions the need for ecological safety during seizure or disposal. That silence, again, is telling. What's even more striking is how little national policy has evolved to meet this complex, cross-sectoral problem. Initiatives like **Pharma Vision 2020** and the **Digital Drug Regulatory System** have focused on drug quality, supply chain integrity, and traceability. These are important goals, to be sure. But they don't include any reference to environmental safety. Likewise, environmental frameworks like the **National Action Plan on Climate Change (NAPCC)** or the **National Environment and Health Policy** don't mention pharmaceuticals as a risk factor—even though drug waste and pharmaceutical pollution are clearly emerging as real-world threats.[28]

So what we're left with is two policy spheres moving along parallel tracks, with barely any intersection. Drug regulators worry about health, environmental regulators worry about pollution, and neither seems to have the tools—or perhaps the mandate—to talk to the other. This isn't a unique problem to India. But other regions have started to respond. For instance, in the **European Union**, laws like **Directive 2008/98/EC** and **Regulation (EU) 2019/6** mandate **Environmental Risk Assessments (ERA)** before a new pharmaceutical product is approved. Some EU nations have even gone a step further by introducing **Extended Producer Responsibility (EPR)**, which makes pharmaceutical companies responsible for collecting and safely disposing of unused or expired medicines. These systems don't eliminate the problem, of course—but they at least acknowledge it. India, by contrast, has no such EPR framework in place for pharmaceuticals—meaning once a drug is sold, or faked, there's no obligation to track where it ends up.

Another big barrier is the lack of hard data. To this day, there has been no national study to quantify how counterfeit pharmaceutical production affects the environment in India. Without real figures—without a baseline—it's extremely difficult to build a case for regulatory reform. Environmental harm caused by counterfeiters isn't recorded in drug-related judgments, and violations of pollution norms by these units are rarely, if ever, prosecuted. This legal silence creates a kind of policy paralysis. If nobody measures the damage, and nobody documents it, then it's as though the problem doesn't exist. At least, not officially.

At a broader level, the laws that govern the pharmaceutical sector in India—while quite comprehensive in some areas—are simply not equipped to handle the environmental spillover from the counterfeit trade. They were designed, understandably, with consumer safety in mind. But the world has changed. The scale of informal pharmaceutical production, the complexity of online markets, and the environmental cost of unregulated manufacturing—all of this demands a fresh legal lens.

To move forward, India needs to **develop an integrated regulatory approach**. This could begin by amending the Drugs and Cosmetics Act to explicitly include provisions that address environmental damage from illegal pharmaceutical production. Inter-agency coordination needs to become the norm, not the exception. Environmental officers should be included in large-scale raids on counterfeit drug units. Joint training sessions and shared data platforms between pollution control boards and drug regulators would also go a long way in bridging the communication gap.[29]

Disposal protocols must be updated—urgently. There should be mandatory environmental reviews before seized drugs are destroyed, and pollution control boards should sign off on the methods used. More ambitiously, India should consider piloting an **EPR-like framework** for pharmaceutical companies, possibly starting with high-risk drugs like antibiotics and steroids that have known ecological impacts.

In the end, the production and disposal of counterfeit medicines in India is no longer just a matter of public health or law enforcement. It's an environmental issue too—one that, if left unchecked, could lead to long-term damage to soil, water, and biodiversity. The laws we currently have were not built for this. That's not a failure so much as a signal: it's time for an upgrade.[30]

2. Environmental Protection Laws And Their Disconnect From Counterfeit Pharmaceutical Enforcement

India's core environmental laws—the **Environment (Protection) Act, 1986**, the **Water (Prevention and Control of Pollution) Act, 1974**, and the **Air (Prevention and Control of Pollution) Act, 1981**—are often cited as robust tools for pollution control. And in many ways, they are. These laws give wide-ranging authority to government bodies to monitor pollution, penalize violations, and even shut down polluting operations when necessary. They also led to the formation of pollution control boards at both central and state levels, with powers to set standards, inspect facilities, and enforce compliance. But here's the catch: none of these laws explicitly deal with pollution that comes from illegal or unlicensed pharmaceutical manufacturing—especially the kind connected to counterfeit drug production.

That's a major oversight. Because while these regulations are equipped to handle pollution from formal industries—those with registered addresses, valid licenses, and regulatory files—they fall short when it comes to what's happening in the unregulated shadows. Counterfeit pharmaceutical operations, by their very nature, don't appear in official databases. They don't apply for pollution permits. They don't submit to inspections. And so, quite predictably, they escape environmental scrutiny entirely.[31]

Pollution control boards, in practice, engage almost exclusively with industries that are visible and trackable. If an entity doesn't exist on paper, it doesn't exist for them at all. Meanwhile, enforcement under the **Drugs and Cosmetics Act** is laser-focused on health and safety concerns—rightly so, but also somewhat narrowly. Drug inspectors are not trained to recognize or document environmental violations, nor are they legally obligated to report such violations even if they encounter them during a raid or site visit. The end result is a fractured enforcement landscape where two arms of regulation—public health and environmental protection—are working in parallel but without contact, leaving large gaps in accountability.[32]

And then there's the matter of waste. India's **waste management framework**, particularly the **Biomedical Waste Management Rules, 2016**, and the **Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016**, is comprehensive in many respects. It outlines how hospitals, diagnostic labs, and licensed pharma units should handle everything from expired drugs to toxic chemical residues. These rules emphasize traceability, segregation, safe storage, and final disposal—all necessary steps to prevent environmental harm.

But once again, these frameworks are only designed for formal actors. If you're not legally recognized—say, a hidden factory producing fake antibiotics in a semi-urban warehouse—then these rules don't even

acknowledge your existence. There is no clause that anticipates unlicensed pharmaceutical waste. No mechanism for tracking it. And certainly no plan for how to clean it up.[33]

This becomes painfully clear when enforcement agencies do succeed in shutting down such operations. What happens to the seized drugs? The leftover raw materials? The chemical drums lying around the site? Unfortunately, the answer is often ad hoc destruction: open burning, chemical dumping, or quick burial in landfills—practices that may do more environmental damage than the factory itself. In many instances, local police or drug inspectors are simply not equipped with the expertise or resources to handle this kind of hazardous waste safely. They're doing their job as best they can, but environmental cleanup isn't part of their training—or their mandate.

That disconnect extends into the courtroom as well. When cases involving counterfeit medicines reach the judicial system, the focus typically stays on product safety, fraud, and health risks to consumers. Rarely, if ever, do courts ask about the environmental impact of these operations. There are no environmental audits submitted as evidence. No discussion of cleanup responsibilities. No ecological fines levied. It's as if pollution doesn't enter the conversation at all—because legally speaking, it often hasn't been framed as part of the crime.

This silence, both legal and institutional, is more than just a regulatory gap. It's a kind of systemic oversight that allows one half of the damage caused by counterfeit medicines to go unrecognized. For communities living near such clandestine operations—many of them in economically vulnerable or environmentally sensitive areas—the consequences can be devastating. Polluted groundwater. Toxic air. Soil degradation. And yet, no legal pathway exists for these communities to seek environmental restitution, because environmental harm, officially, was never acknowledged in the first place.

You might expect that recent reforms would begin to address this blind spot. But unfortunately, even the latest proposals—like the **draft amendments to the Drugs and Cosmetics Act** and the newer **Drugs, Medical Devices and Cosmetics Bill**—fall into the same trap. These reform efforts are aimed at modernization: strengthening regulation, enhancing transparency, improving drug quality surveillance. And to their credit, they do take significant steps toward better health protection and digital traceability. But not once do they speak to the environmental consequences of pharmaceutical crime. Not in the preamble, not in the enforcement sections, not even in passing. This is, quite frankly, a missed opportunity.[34]

At a time when environmental degradation is no longer a distant worry but a present and accelerating crisis, the failure to integrate ecological thinking into pharmaceutical regulation feels shortsighted. A few simple additions—like requiring environmental risk assessments during large seizures, or including pollution violations in the definition of pharmaceutical offences—could begin to close the gap. And yet, those additions remain absent.

If there's one thread running through all of this, it's fragmentation. Fragmentation between sectors, between agencies, between legal codes. Public health and environmental safety are deeply intertwined, but our laws don't treat them that way. And unless that changes—unless we start building cross-sectoral mandates, shared data platforms, and inter-agency response teams—the regulatory blind spots will remain. Not because the laws are weak, necessarily, but because they were never designed to see what's now in front of us.

We're entering a phase where the environmental costs of counterfeit drug production can no longer be ignored. The pollution they cause is not incidental—it's structural, baked into the way these operations function. They use unregulated processes, cheap solvents, unsafe disposal methods, and poor containment. And all of this adds up to real ecological damage. Water that becomes undrinkable. Crops that don't grow. Communities that fall sick from chemical exposure. So, it's time to rethink how we structure our laws and protocols. Not from scratch—but with serious intent to connect the dots between environmental risk and pharmaceutical enforcement. Without that shift, counterfeit drug production will remain a public health emergency on the surface, and an invisible environmental crisis just beneath it.

The environmental fallout from counterfeit pharmaceuticals is slowly, almost reluctantly, finding space in global policy discourse. While public health understandably takes center stage, the environmental aspect is often an afterthought—if considered at all. Still, some jurisdictions, particularly the European Union and the

United States, have started grappling with this issue in ways that, although somewhat fragmented, provide useful models. These aren't perfect blueprints by any stretch, but they do offer some lessons worth considering—especially for countries like India where the problem is both large in scale and deeply entrenched in regulatory blind spots.

3. Legislative Framework In Leading Countries

Counterfeit pharmaceuticals present a dual-edged threat—jeopardizing public health while also causing substantial, albeit often overlooked, environmental harm. Despite the severity of this issue, neither the European Union nor the United States has enacted a standalone law specifically addressing the ecological consequences of counterfeit drugs. However, both jurisdictions have developed an ecosystem of overlapping legal instruments, strategic directives, and inter-agency collaborations that serve, in a piecemeal but effective way, to mitigate the environmental risks posed by fake pharmaceuticals. In the EU, laws such as the Waste Framework Directive (Directive 2008/98/EC) indirectly apply to counterfeit drugs when they are categorized as hazardous waste, enforcing strict rules for their storage, transport, and disposal. Similarly, the Falsified Medicines Directive (2011/62/EU), though aimed at ensuring drug authenticity and protecting consumers, indirectly limits the spread of counterfeit drugs—and, by extension, the chance of their illegal dumping in natural ecosystems. Countries like Germany and Sweden have further expanded the scope of these directives, using them creatively to support environmental clean-up following raids on illicit pharmaceutical operations. The EU's broader policy vision is complemented by initiatives like the 2019 Strategic Approach to Pharmaceuticals in the Environment, which, while primarily addressing legal pharmaceuticals, briefly acknowledges the role of counterfeit products in ecosystem contamination. On the other hand, the United States adopts a more reactive but forceful strategy, relying on environmental laws such as the Resource Conservation and Recovery Act (RCRA) for hazardous waste management and the Superfund law (CERCLA) for environmental remediation. These are supported by multi-agency collaboration between the FDA, DEA, and EPA, allowing for integrated enforcement that includes both criminal prosecution and site clean-up. Although no dedicated law exists on either side of the Atlantic, the EU's regulatory, prevention-based approach and the U.S.'s enforcement-heavy framework collectively demonstrate how existing legal tools can be adapted creatively to tackle the environmental fallout of counterfeit pharmaceuticals—a lesson particularly relevant for countries like India.

3.1 Legal & Strategic Approaches To Environmental Harm From Counterfeit Drugs

The production, distribution, and disposal of the counterfeit medicines or pharmaceuticals poses relevant environmental risks, which includes various hazards such as chemical pollution, waste accumulation and ecosystem contamination. In order to mitigate such threats, the regulatory frameworks in the European Union (EU) and the United States (US) combines the pharmaceutical safety laws with environmental protection measures as well. The EU employs a multi-layered approach by integrating the directives such as the Waste Framework Directive (2008/98/EC)[35] and the Falsified Medicines Directive (2011/62/EU)[36] to ensure the traceability and proper disposal, while on the other hand, agencies like Europol facilitate cross-border enforcements. The table as below compares these legal and strategic mechanisms and highlighting how environmental regulations are increasingly used to combat pharmaceutical crime while also safeguarding public health and ecosystem.

Jurisdiction	Key Legal Instruments	Primary Focus	Counterfeit-Specific Relevance	Enforcement/Implementation Mechanism
EU	Waste Framework Directive (2008/98/EC)	Waste management	Applies to counterfeit drugs when considered hazardous waste	Enforces safe handling, transport, and disposal

	Falsified Medicines Directive (2011/62/EU)	Drug authenticity and traceability	Reduces counterfeits via packaging and tracking	Prevents entry into supply chain
	REACH Regulation	Chemical safety	Identifies hazardous substances in fake drugs	Used as benchmark in enforcement
	Strategic Approach to Pharmaceuticals in the Environment (2019)	Pharmaceutical pollution	Briefly acknowledges counterfeit contamination	Promotes take-back schemes, monitoring
	National Adaptation (e.g., Germany, Sweden)	Creative application of EU laws	Enables cleanup post illegal pharma lab raids	National agencies apply directives flexibly
	Europol + European Medicines Agency	Cross-border enforcement	Targets counterfeit production and environmental damage	Collaborative cleanups and raids
US	Resource Conservation and Recovery Act (RCRA)	Hazardous waste control	Covers counterfeit drug waste if hazardous	Ensures proper disposal and containment
	Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA/Superfund)	Pollution cleanup	Covers illegal lab contamination	EPA authorized to clean and recover costs
	Secure and Responsible Drug Disposal Act (2010)	Drug take-back	Can include expired/counterfeit drugs	Public programs for safe disposal
	Toxic Substances Control Act (TSCA) & FIFRA	Regulates chemical use	Applies if banned chemicals used in counterfeit labs	Supports enforcement flexibility
	FDA-OCI + DEA + EPA Collaboration	Multi-agency action	Jointly investigate and clean counterfeit drug sites	Adds environmental charges to criminal cases

Both the European Union and the United States have developed very distinctive yet very complementary legal and strategic approaches to address the environmental harm posed by counterfeit pharmaceuticals in their respective countries. The EU adopts a preventive and regulation-driven model that incorporates pharmaceutical safety in the environmental directives, such as the 'Waste Framework Directive' and the 'Falsified Medicines Directive', so as to ensuring the traceability, proper disposal, and reduced market entry of counterfeit drugs. Instruments such as 'REACH' and national adaptations of it allows for flexible

responses, including post-raid cleanups with enforcement facilitated through inter-agency collaboration between Europol and the European Medicines Agency.[37]

In contrast to this, the US model is more enforcement-heavy, relying mostly on the environmental laws like the Resource Conservation and Recovery Act (RCRA) and CERCLA to clean up contamination from the illegal labs and hold the violators accountable. Additional laws such as the Secure and Responsible Drug Disposal Act, 2010 and coordinated actions by the FDA's Office of Criminal Investigations, DEA, and EPA enable effective drug take-backs and prosecutions that can include environmental charges. This table below presents a comparison between the **European Union (EU)** and **United States (US)** in their legal and strategic responses towards the environmental risks that is posed by counterfeit pharmaceutical:

Aspect	European Union	United States
Approach Style	Preventive, regulatory, traceability-based	Reactive, enforcement-heavy
Legal Structure	Patchwork of directives and policies	Overlapping environmental statutes
Inter-Agency Cooperation	Europol, EMA, national bodies	FDA-OCI, DEA, EPA
Environmental Focus	Indirect, through pharmaceutical waste and safety directives	Direct cleanup via CERCLA and RCRA
Applicability to Counterfeits	Indirect but adaptable	Covers counterfeits under broader statutes
Policy Model	Structured improvisation	Pragmatic enforcement

It can be analyzed from the comparison that while the EU prioritizes preventions and regulations and a systematic collaboration between the, the US emphasises more upon the enforcement and direct environmental remediation. Both models offer lessons for integrating anti-counterfeiting and environmental protection efforts in global drug policy.

4. Recommendations For Suitable Policy Framework In India

The problem of counterfeit medicines in India has long been understood as a serious public health crisis. However, what is often overlooked—or perhaps just not spoken about enough—is the environmental harm that accompanies these illegal pharmaceutical activities. The unregulated manufacturing processes, unsafe disposal practices, and hidden chemical dumping all contribute to a quieter but deeply dangerous form of pollution. The laws we currently have, although substantial on their own, don't seem to talk to each other. The agencies responsible for drug safety and those meant to protect the environment operate in silos, leaving the country without a coordinated strategy to tackle the full scope of the problem.[38]

Key Issue	Proposed Solution	Responsible Agencies	Expected Outcome
Inter-Agency Coordination	Create a National Task Force on Counterfeit Medicines & Environmental Risk	MoHFW, MoEFCC, State Agencies, CDSCO, CPCB, Investigative Agencies	Streamlined raids, shared intelligence, and clearer accountability.
Enforcement Gaps	Establish a Joint Enforcement Protocol for raids (environment + drug inspectors)	CDSCO, SPCBs/Pollution Control Boards, Drug Inspectors	Real-time hazard detection (chemical dumping) and prosecution under environmental laws.

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Waste Disposal	Issue Integrated Seizure & Disposal Guidelines for counterfeit medicines	MoHFW, CPCB, Hazardous Waste Facilities	Reduced secondary contamination via certified disposal methods.
Data Deficits	Launch a National Database on Environmental Offences Linked to Counterfeit Drugs	CDSCO, CPCB, NIC	Data-driven enforcement, hotspot mapping, and trend analysis.
Capacity Building	Conduct inter-agency training on pharmaceutical waste & counterfeit detection	NIHFW, NETI, State Training Institutes	Shared technical language between drug/environment regulators.
Public Engagement	Create a public reporting system (portal/toll-free number) for suspicious activity	Local Authorities, MoEFCC, MoHFW	Proactive enforcement via community alerts.
Traceability	Implement National Pharmaceutical Traceability Framework (QR codes/blockchain)	CDSCO, MeitY, Pharma Industry	End-to-end supply chain transparency; reduced counterfeit circulation.
Financial Support	Offer subsidies/tax incentives for MSMEs adopting traceability tech	Ministry of Finance, Digital India Program	Faster compliance among small manufacturers.
Extended Producer Responsibility (EPR)	Introduce EPR Guidelines for Pharmaceutical Waste (collection targets)	MoEFCC, CPCB, Pharma PROs	Industry accountability for safe disposal of expired/unsold drugs.
Scientific Research	Fund National Environmental Toxicology Research Initiative (fake drug impacts)	ICMR, CSIR, MoEFCC, CDSCO	Evidence-based policies on ecological damage from counterfeit drugs.

5. CONCLUSION

The legislative framework in India, as it currently stands, tends to focus rather narrowly on the health and criminal dimensions of counterfeit pharmaceuticals. What it fails to adequately recognize—let alone address—is the broader, and quite urgent, environmental damage that often accompanies these activities. Unregulated manufacturing, frequently carried out in informal or illegal facilities, results in toxic discharges that can seriously contaminate water sources, soil, and even air. Yet, strangely enough, the law remains largely silent on this front. This gap in environmental accountability leaves enforcement agencies without the necessary tools to respond to pollution caused by such operations, allowing these violators to pollute with little to no fear of environmental consequences.[39]

The urgency of the situation calls not just for incremental reforms, but for a thoughtful and coordinated overhaul—one that begins by rethinking how environmental risk is integrated into drug regulation and enforcement. Environmental protection cannot remain disconnected from pharmaceutical governance. What's really needed is a policy framework that mandates environmental due diligence as a routine part of drug-related enforcement, while also encouraging structured cooperation between drug regulators and pollution control bodies. Without this sort of institutional and legal integration, India risks facing not just a

public health emergency driven by toxic, falsified drugs, but also a slow-burning ecological crisis—one that could quietly erode the health of communities and ecosystems for years to come.[40]

The present moment feels like something of a crossroads. India now has a chance to rethink how it responds to the counterfeit drug problem—not just as a threat to human health, but also as a direct contributor to environmental degradation. In this context, digital tools such as QR codes and blockchain-based tracking systems could play a transformative role. When implemented well, these technologies make it far easier to track the life cycle of pharmaceutical products, reducing opportunities for counterfeits to enter the supply chain. More importantly, they create a system of traceability that extends beyond market access to waste disposal, ensuring that expired or recalled drugs don't quietly reappear as environmental hazards. Of course, introducing these tools at scale will require coordination across ministries, consistent legal backing, and public-facing infrastructure—but the benefits, both in terms of deterrence and environmental accountability, are difficult to ignore.[41]

The broader point here is that environmental governance cannot continue to operate in a silo. The damage caused by counterfeit pharmaceutical operations—chemical dumping, unsafe waste disposal, unregulated emissions—goes well beyond what health authorities alone can manage. A piecemeal or single-agency response will almost certainly fall short. Instead, India needs a more cohesive, interlinked regulatory architecture, one that brings together agencies responsible for drug control, environmental safety, law enforcement, and public health. The logic is simple enough: if the problem itself is interdisciplinary, the solution must be as well. Inter-agency cooperation, in this sense, is not just a procedural upgrade—it is a strategic necessity if India wants to address the problem in its entirety.

The environmental risks tied to counterfeit medicines are no longer marginal. They have become central to the wider conversation around pharmaceutical regulation and sustainability. To respond meaningfully, India could consider introducing a form of **Extended Producer Responsibility (EPR)** that is tailored specifically to pharmaceuticals.[42] At its core, such a system would compel manufacturers to take responsibility for the collection and environmentally safe disposal of expired, unused, or counterfeit drugs. The logic is two-fold: not only does this create a closed-loop system that encourages safer waste management, it also tightens control over how drugs move after they leave the formal market—reducing the pathways through which counterfeits re-enter circulation. When properly enforced and tied to traceability systems, EPR has the potential to reshape how the pharmaceutical sector engages with its environmental footprint.

However, regulation and technology are only part of the solution. What continues to be missing—and urgently needed—is a robust knowledge base rooted in environmental science. At present, India lacks detailed, empirical data on how counterfeit pharmaceuticals degrade in the environment, what residues they leave behind, or how these chemicals interact with ecosystems. This kind of research is critical.[43] Without it, enforcement will remain reactive, and environmental standards will lack the scientific grounding required for effective implementation. A sustained national investment in environmental toxicology—perhaps led by a partnership between the Ministry of Environment, the Central Drugs Standard Control Organization, and scientific institutions—could provide the evidence base for smarter, more responsive policymaking.

In the end, confronting the environmental fallout from counterfeit drugs is not just about plugging a legal loophole—it's about shifting how we think about public health, environmental risk, and governance. If India can begin to see these issues not as isolated challenges, but as part of an interconnected system, it may be possible to craft policies that are both more effective and more sustainable in the long run. This won't happen overnight, of course. But with the right combination of legal reform, digital innovation, inter-agency cooperation, and scientific inquiry, India could very well position itself as a global leader in addressing this deeply complex problem at its roots.

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