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The Leaking Pipeline

How India Loses Nearly 24% of Its Domestic Pharmaceutical Value Before It Generates a Health Outcome

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List of Abbreviations

ABDM	Ayushman Bharat Digital Mission
AMR	Antimicrobial Resistance
API	Active Pharmaceutical Ingredient
CAG	Comptroller and Auditor General of India
CDSCO	Central Drugs Standard Control Organization
CGHS	Central Government Health Scheme
CMSD	Central Medical Stores Depot
DOP	Department of Pharmaceuticals
DVDMS	Drug and Vaccine Distribution Management System
EPR	Extended Producer Responsibility
EU	European Union
FEFO	First Expiry, First Out
FY	Financial Year
GMP	Good Manufacturing Practices
HIV	Human Immunodeficiency Virus
IT	Information Technology
LMIC	Low- and Middle-Income Countries
MoHFW	Ministry of Health and Family Welfare
NHM	National Health Mission
NSQ	Not of Standard Quality
OOPE	Out-of-Pocket Expenditure
PHC	Primary Health Centre
PLI	Production Linked Incentive
PMBJP	Pradhan Mantri Bhartiya Janaushadhi Pariyojana
PRO	Producer Responsibility Organisation
QR	Quick Response (Code)
SDC	State Drug Controller
SOP	Standard Operating Procedure
TNMSC	Tamil Nadu Medical Services Corporation
UPMSCL	Uttar Pradesh Medical Supplies Corporation Limited
USFDA	United States Food and Drug Administration
WHO	World Health Organization

Executive Summary

India plays a critical role in global healthcare as the "Pharmacy of the World," supplying affordable medicines, vaccines, and generic pharmaceuticals to more than 200 countries[1]. The country accounts for nearly 20% of global generic medicine consumption, ranks third globally in pharmaceutical production by volume, and produces 60–70%[2] of the world's vaccines. Its extensive manufacturing base, strong regulatory compliance, and large network of USFDA-approved and WHO-GMP-certified facilities have established India as a trusted pharmaceutical partner worldwide.

The pharmaceutical sector is both an economic and strategic asset. Pharmaceutical exports exceeded USD 30 billion in FY 2024–25[3], while domestic consumption surpassed **INR 2,01,372 crore in FY 2023–24[4].** Indian medicines have transformed access to affordable healthcare globally, particularly through vaccines, generic medicines, and antiretroviral therapies.

Over the past decade, India has strengthened pharmaceutical manufacturing, expanded domestic API production, improved medicine access, and invested in digital health systems. However, while the country has built a robust production and distribution ecosystem, it has yet to establish a comprehensive post-market medicine management system.

As a result, significant value is lost throughout the medicine lifecycle. Substandard and spurious medicines continue to circulate, medicines expire unused in households and public facilities, government inventories face overstocking and wastage, and defective products cannot always be recovered efficiently due to the absence of a nationwide recall and medicine recovery architecture.

This report estimates that nearly **INR 48,000 crore is lost annually across India's pharmaceutical ecosystem** due to four major sources of leakage:

1. **Substandard, spurious, and adulterated medicines**
2. **Unused household medicines**
3. **Government stock expiry and overstocking**
4. **Downstream treatment failure costs**

Together, these losses represent nearly one-fourth of India's annual pharmaceutical consumption expenditure. At the core of these inefficiencies is the absence of an integrated pharmaceutical accountability framework that combines mandatory recall systems, medicine take-back mechanisms, digital traceability, and reverse logistics infrastructure.

Strengthening pharmaceutical accountability presents a major opportunity. Effective recall and recovery systems can improve patient safety, reduce healthcare costs, minimize medicine wastage, enhance inventory management, and improve procurement efficiency. For the pharmaceutical industry, stronger post-market oversight can increase supply-chain transparency, reduce reputational risks, align India with emerging global standards, and strengthen international confidence in Indian medicines.

Many countries have already adopted closed-loop pharmaceutical systems that integrate serialization, recall governance, pharmacy take-back programs, and digital inventory management. As global healthcare systems increasingly prioritize traceability and lifecycle accountability, India has an opportunity to establish similar mechanisms at scale.

Even modest reductions in current leakages could generate substantial fiscal savings, improve medicine access, reduce out-of-pocket expenditure, and strengthen public trust in the healthcare system. As India advances toward the vision of **Viksit Bharat 2047**, pharmaceutical leadership will depend not only on producing medicines at scale, but on ensuring that every medicine procured, distributed, and consumed delivers its intended health value.

This report concludes that pharmaceutical accountability should be treated as a national health and economic priority. Establishing an integrated accountability framework, implementing mandatory recall systems, and expanding medicine take-back initiatives will be essential to reducing losses and reinforcing India's position as a global pharmaceutical leader.

Introduction

India is a leading global pharmaceutical economy, supplying[5] affordable medicines to over 200 countries[6] and supporting access to vaccines, antibiotics, generics, and essential therapies. As the world's third-largest pharmaceutical[7] producer by volume, India continues to strengthen its position through large-scale manufacturing, competitive pricing, and a growing domestic market.

In the past decade, India has developed one of the world's most extensive pharmaceutical distribution networks. Public initiatives such as the NHM, state procurement corporations, CGHS, PMBJP, and other welfare programs have expanded access nationwide. At the same time, private pharmacies, hospital networks, and digital health platforms have extended supply chains into both urban and rural areas. Policy reforms, including PLI schemes, the promotion of domestic API manufacturing, the strengthening of Jan Aushadhi Kendras, and the expansion of digital health infrastructure under ABDM, reflect India's goal to become a globally trusted healthcare ecosystem.

Despite India's manufacturing and distribution successes, a major challenge remains unaddressed.

India's robust pharmaceutical production and distribution lack a fully accountable post-market management system. Value is lost before medicines reach patients. Substandard and expired medicines enter circulation, and unused government stock often goes to waste. Households discard medicines due to changes in medication regimens, non-adherence, or stockpiling. The main issue is the lack of a nationwide system for recall, retrieval, redistribution, or safe disposal once medicines reach the market.

Without a structured system for recall, redistribution, or safe disposal, medicines that fail standards or go unused accumulate across the supply chain until they expire or are discarded.

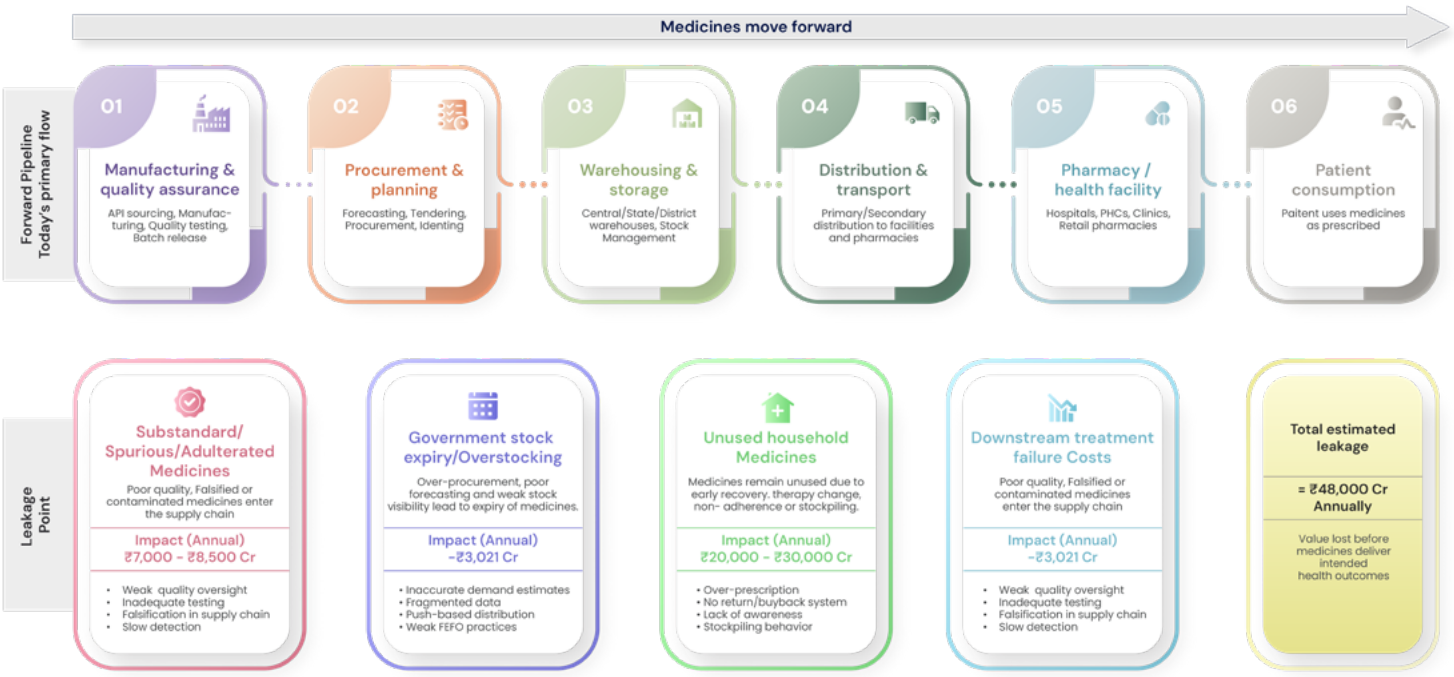
This report estimates that an estimated INR 35,000–55,000 crore is lost annually, with a central estimate of approximately **INR 48,000 crore** in India's pharmaceutical ecosystem before medicines deliver their intended therapeutic value. This accounts for almost **24% of total pharmaceutical expenditure**, based on annual domestic consumption of approximately **INR 2,01,372 crore.**

Leakage occurs throughout the medicine lifecycle, resulting in hidden costs to public health and households.

Key Pharmaceutical Leakage Buckets

The estimated **INR 48,000 crore** in losses falls into four main categories:

The Pharmaceutical Value Chain and Leakage Points



Quality failures increase downstream treatment costs when defective batches cannot be quickly traced, recalled, and removed from circulation. Government stock expiry, meanwhile, reflects weak inventory visibility and limited mechanisms to transfer excess or near-expiry medicines to locations with demand.

The challenge has shifted from production capacity to ensuring pharmaceutical accountability. To address this, India must now focus on establishing systems that ensure medicines are traceable, effective, and accountable throughout their lifecycle, from procurement to patient use, recovery, and safe disposal. India's future pharmaceutical leadership will depend not only on production volume, but also on how efficiently and safely medicines contribute to successful health outcomes.

Chapter 1: Government Stock Expiry / Overstocking

Overstocking is the procurement and accumulation of medicines in quantities significantly exceeding actual consumption or demand. It arises from inaccurate demand forecasting, irrational indents by facilities, centralized procurement mismatches (where supplies are pushed without aligned needs), acceptance of short-shelf-life stocks, and weak inventory controls. In government setups, this often stems from «push» supply mechanisms rather than «pull» or consumption-based models, leading to prolonged holding periods and eventual expiry.

In India's public health system, this issue is well-documented through Comptroller and Auditor General (CAG) audits. In Uttar Pradesh, drugs worth INR 27.06 crore expired in central and district warehouses of the Uttar Pradesh Medical Supplies Corporation Limited (UPMSCL) between March 2020 and March 2022. This occurred against a total procurement expenditure of around INR 1,978.50 crore during 2019-22. Key causes included acceptance of supplies with low shelf life (e.g., less than 80% remaining), refusals by consignee facilities due to lack of space or no demand, and over-procurement based on inflated or irrational indents. UPMSCL accepted drugs worth INR 46.90 crore with less than 80% shelf life and even relaxed norms for some suppliers[8].

In Telangana, expired drugs valued at INR 390.26 crore were not replaced timely by suppliers, as per e-Aushadhi data, leading to massive losses. Additionally, drugs with very short remaining shelf life (1-89 days) worth INR 17.13 crore were issued to facilities. In Tamil Nadu, short-shelf-life medicines worth INR 11.12 crore expired in TNMSC stocks due to delayed supplies from 185 manufacturers between 2016-21[9].

The consequences due to overstocking remain multifaceted. Excess stock burdens limited storage infrastructure increases holding costs, and leads to improper disposal, raising environmental concerns. Capital is locked in unusable inventory, diverting funds from new procurements, infrastructure, or other health priorities. Studies emphasize that poor quantification and inventory practices directly correlate with expiry wastage in low- and middle-income country (LMIC) public systems[10].

Overstocking in some warehouses coexists with chronic stock-outs in others, a «feast or famine» scenario. In UP, stock-outs of essential drugs lasted up to 1,400+ days in test-checked facilities, compromising patient care in a system promising free medicines. Expired or near-expiry drugs may lose efficacy or develop harmful degradation products, leading to treatment failures, adverse reactions, or increased antimicrobial resistance

India's drug recall framework, managed by the Central Drugs Standard Control Organization (CDSCO) and state licensing authorities, is primarily voluntary and guided by the 2012/2017 Guidelines on Recall & Rapid Alert System. The guidelines classify recalls (Class I-III based on risk) but lack mandatory timelines, strong enforcement, a centralized public portal, or effective reverse logistics for public sector stocks[11]. This weakness directly amplifies overstocking-related expiry in government systems.

Public procurement contracts often include replacement clauses for short-shelf-life or defective supplies, but enforcement is poor. CAG reports note that suppliers frequently deliver low-shelf-life stocks, and facilities/ warehouses cannot easily return or redistribute excess, leading to accumulation and expiry. In UP, rejected stocks were sometimes diverted but still expired due to lack of demand. Fragmented IT systems (e.g., incomplete DVDMS rollout) hinder real-time visibility of stocks across facilities. Overstocked items remain idle while shortages persist elsewhere[12]. India has debated a mandatory drug recall law since 1976, but none exists nationally. Recalls for substandard (NSQ) drugs are often delayed or ineffective, allowing problematic batches to enter and linger in the public supply chain. There is limited public transparency or mandatory effectiveness checks, unlike stricter systems in the US (FDA) or EU[13][14]. The absence of mandatory recall legislation reflects the complexity of aligning manufacturer interests, regulatory capacity, and central-state jurisdiction. The policy proposals later in this report are designed with this constraint in mind, building on existing infrastructure and voluntary frameworks rather than requiring new legislative architecture from scratch.

Over-procurement without robust consumption data

combines with absent proactive near-expiry recall/ redistribution mechanisms. This turns excess inventory into waste. Transitioning to consumption-based models (as UPMSCL attempted in 2022) helps, but weak recall/ redistribution undermines it. Strengthening this through mandatory supplier take-back, digital tracking, and a national recall portal with public alerts could significantly mitigate expiry from overstocking.

Financial losses from this issue are substantial, recurring, and strain public health budgets. Repeated procurement to cover shortages, disposal expenses, quality testing gaps, and administrative overhead multiply the burden. Older private sector estimates placed annual expiry losses around INR 500 crore, while public systems face added pressures from free-distribution mandates and bureaucratic processes[15]. Nationally, while comprehensive aggregates are underreported, these losses reduce the efficiency of schemes like the National Health Mission and erode value-for-money in medicine procurement. Broader studies highlight that expired medicine wastage imposes significant economic strain on public health facilities, including disposal costs and lost opportunities[16].

A case study highlights how even a single medical store can lose around INR 50,000 per month in expired stock, primarily due to over-ordering, weak inventory controls, and slow-moving medicines. If similar inefficiencies are extrapolated across India's vast public health procurement network of warehouses, district stores, hospitals, PHCs, and dispensaries, the cumulative losses can be substantial. Using India's annual pharmaceutical consumption base of INR 2,01,372 crore and applying a conservative 1.5% leakage assumption for public-sector expiry, overstocking, and non-moving inventory, the annual financial loss would be approximately INR 3,021 crore. This reflects medicines procured using public funds that expire before reaching patients. Beyond direct wastage, these losses create secondary costs through emergency local purchases, stock-outs of essential medicines, higher logistics burden, and delayed patient treatment. Government stock expiry therefore represents a silent, but material drain on scarce health budgets and highlights the need for stronger demand forecasting, FEFO-based inventory systems, and real-time digital stock visibility[17].

Expert Quote

"Ensuring supply chain integrity is fundamental to both patient outcomes and the long-term credibility of the pharmaceutical ecosystem. As supply chains become increasingly global, complex, and interdependent, the risks, from counterfeiting to product leakages, require a more systemic response. This goes beyond isolated interventions to building end-to-end transparency, anchored in digital traceability, strong governance frameworks, and accountable partnerships across the value chain.

At a broader level, integrity and resilience must be designed into the system itself—supported by sustainable practices, data-driven decision-making, and aligned regulatory efforts. Ultimately, the future of pharma supply chains will be defined not just by efficiency, but by trust, transparency, and their ability to reliably serve patients at scale"

- Mr. Ramesh Swaminathan, Executive Director, Global CFO, Head of IT and API Plus SBU

Chapter 2: Unused Household Medicines

Unused household medicines represent a significant yet often overlooked form of leakage in India's healthcare ecosystem. These are prescription or over-the-counter drugs purchased by households but left unconsumed due to reasons such as early patient recovery, treatment plan changes, side effects, over-prescription (e.g., full packs when partial doses suffice), stockpiling, or improper storage leading to expiration. This issue is widespread in India, where high out-of-pocket expenditure (OOPE) on medicines already strains household finances, and systemic gaps in awareness, dispensing practices, and waste management compound the problem[1819]. Leftover medicines appear in 53–75.8% of households, with one study finding them in 75.8% of 165 surveyed houses. Up to 70% of medicines bought in the last three years may go unused in affected homes, and 87–95% of households store medicines at home. Antibiotics, analgesics, and antipyretics are commonly left over medicines in a household[202122].

77–95% of people discard unused or expired medicines in household trash/dustbins, while smaller shares flush them into toilets/sinks or bury them. Very few return them to pharmacies. Only a minority receive guidance from physicians, and awareness of proper disposal remains low (e.g., 75% in one study had never sought information). Consequences of these actions are beyond individual waste. Environmentally, pharmaceuticals leach into soil, landfills, and water bodies, contributing to pharmaceutical pollution. Antibiotics in the environment drive antimicrobial resistance (AMR) by promoting resistant bacteria, a major public health crisis in India. This leads to harder-to-treat infections, prolonged hospitalizations, higher mortality, and increased healthcare costs. Additional risks include accidental poisoning (especially in children), drug diversion/misuse, and harm to aquatic life and ecosystems[23].

The primary reason for widespread household wastage and improper disposal of unused/expired medicines in India is the near-total absence of convenient, accessible, and nationwide recall or take-back (recovery) systems for end-consumers (households). While upstream supply chain actors (manufacturers, wholesalers, retailers) have some return protocols, households, which is the the final point of consumption, that are largely left without practical options. Although, CDSCO has issued guidelines promoting take-back programs and safe disposal, implementation is fragmented. Most consumers lack convenient options, leading to accumulation, unsafe disposal, expiration, and systemic leakage[24].

Financially, this creates direct household losses (estimated at INR 200–260 per affected household in sampled studies, scaling nationally to substantial amounts) and indirect burdens on the public health system through elevated treatment costs for resistant infections and pollution-related issues. Medicines form a large share of OOPE (often 60%+ in some estimates), and inefficiencies like this undermine efforts to reduce OOPE and increase government health spending[25].

A recent report indicates that Indian households may waste up to 70% of medicines purchased through expiry, non-use, or improper disposal.

Using India's annual domestic pharmaceutical consumption base of INR 2,01,372 crore, a literal upper-bound interpretation would imply medicines worth nearly INR 1,40,960 crore may remain partially or fully unused. However, not all medicine purchases are wasted entirely, and many households may use only part of a prescription before discontinuation. Therefore, for economic modelling, a more conservative realized-loss assumption of 10% - 15% of total household medicine spend is more credible. This suggests an annual financial leakage of approximately INR 20,000 – INR 30,000 crore through unused household medicines alone. Beyond the direct value loss, unused medicines also create secondary costs through self-medication risks, accidental poisoning, environmental contamination, and the need for repeat purchases when medicines are later required. This makes household medicine wastage one of the largest hidden inefficiencies in the pharmaceutical value chain[26].*

Chapter 3: Substandard Medicines and Penetration of Spurious Adulterated

Substandard medicines are authorised products that fail to meet required quality standards, strength, purity or performance. They may contain the right active ingredient, but in the wrong quantity, may not dissolve properly, may degrade due to poor manufacturing or storage, or may fail quality tests. Falsified or spurious medicines are more serious. These are products that deliberately misrepresent their identity, composition or source. They may carry the name of a legitimate brand or manufacturer, but may contain little, wrong or no active ingredient. WHO defines substandard and falsified medical products in this way, and flags them as a major public health risk, especially in low- and middle-income countries[27].

For India, this issue matters because the country has built global credibility as the "pharmacy of the world", yet quality failures continue to appear in post-market surveillance. CDSCO's monthly alerts regularly identify medicines that are "not of standard quality" or fake, including commonly used products such as antibiotics, antacids, vitamins and pain medicines[28]. Reuters reported that CDSCO flagged more than 50 drugs as substandard or fake in one monthly alert, including widely used formulations such as antacids, paracetamol, antibiotics and calcium/vitamin products[29].

The real leakage does not come only from the existence of poor-quality medicines. The larger problem is that once such medicines enter the market, India does not yet have a uniformly strong, fast and consumer-facing recall and recovery system that can reliably pull every affected batch back from wholesalers, retailers, public facilities and households.

In practice, a medicine may be detected as substandard only after it has already moved through the supply chain. By then, part of the batch may have been sold, consumed, stored in households, or distributed through hospitals and public facilities. Without strong batch-level traceability, instant alerts to pharmacies, reverse logistics, and clear consumer return pathways, the system often reacts after part of the loss has already occurred.

Recent state-level examples show why recall speed matters. Karnataka reportedly reduced the time taken to withdraw substandard medicines from around 30 days to two days after digitising the recall process, suggesting that manual recall systems allow defective medicines to remain in circulation longer[30]. Telangana has also introduced SMS alerts to notify pharmacies and wholesalers when a medicine is declared not of standard quality, indicating that states are beginning to address the recall gap, but these efforts remain fragmented rather than national and uniform[31].

This is why recall and recovery should be treated as a cross-cutting weakness in the chapter. Poor-quality medicines become a financial and public health leakage when the system cannot quickly identify, stop, retrieve and safely dispose of affected stock.

The financial impact of substandard and spurious medicines should be presented as a conservative estimate, not as a direct application of WHO's 10% benchmark. WHO's estimate that nearly 1 in 10 medical products in

low- and middle-income countries may be substandard or falsified gives a sense of the scale of exposure, but not all such medicines translate into full financial loss. Some are detected before use, some may retain partial effectiveness, and not every case leads to complete treatment failure[32].

Using the report's annual domestic pharmaceutical consumption base of approximately **INR 2,01,372 crore,** even a conservative quality-risk exposure creates a material economic burden. If only a part of the at-risk medicine value translates into ineffective treatment, reduced potency, repeat purchases or failed therapy, the direct annual loss from substandard medicines can reasonably be estimated at around INR **5,000 – INR 5,500 crore.**

Spurious and adulterated drug penetration adds another layer of leakage. If even 0.5%–1.0% of the market value is affected by such products, the annual at-risk value would be around INR **1,000–INR 2,000** crore. After accounting for repeat purchases, additional consultations, diagnostics, adverse event management and enforcement costs, the broader financial impact may rise to around **INR 2,000–INR 3,000 crore annually.**

On this basis, the combined financial leakage from substandard, spurious and adulterated medicines can be positioned at approximately **INR 7,000–INR 8,500 crore** per year. This is not only a regulatory problem. It is a hidden fiscal burden on households, public procurement systems and the wider healthcare system.

Chapter 4: Downstream Treatment Failure Costs

It is important to note that downstream treatment failure costs are not an independent leakage stream; they are a consequence of the failures described in the preceding chapters. The estimates below represent the additional expenditure generated by treatment failures, distinct from the direct cost of the failed medicine itself, which is captured in Chapters 1–3. There is limited overlap between these figures, but the combined total should be read as an approximation rather than a precise aggregate.

Downstream treatment failure costs refer to the additional health expenditure that begins **after a medicine fails to deliver the expected clinical outcome.** This may happen because the medicine is substandard, falsified, adulterated, degraded due to poor storage, expired, or clinically ineffective for the patient.

The cost does not stop at the price of the medicine. When treatment fails, the patient often returns to the doctor, buys replacement medicines, undergoes additional tests, shifts to second-line therapy, or in severe cases, requires hospitalization. WHO notes that substandard and falsified medicines can lead to treatment failure, prolonged illness, drug resistance, increased healthcare costs, loss of productivity, and in some cases, death[33].

This makes downstream failure a multiplier cost. The original medicine spend is lost, and a second layer of expenditure is created to correct or manage the failed treatment.

Downstream treatment failure becomes more expensive when weak recall and recovery systems allow risky medicines to remain in circulation for longer. A medicine quality issue may be detected at one point in the system, but unless the affected batch is quickly traced, recalled, and removed from pharmacies, public facilities, informal channels, and households, patients may continue consuming it.

WHO highlights that effective response requires systems that can detect substandard and falsified products already in the supply chain and respond quickly in a way that safeguards patients and the supply chain. In the absence of such closed-loop recovery, the same quality failure keeps generating new treatment failures across multiple patients and locations.

This is especially important for antibiotics, chronic disease medicines, injectables, and high-risk therapies. For antibiotics, failed or incomplete treatment can also contribute to antimicrobial resistance[34], which makes infections harder to treat and increases the need for more expensive and intensive care. WHO estimates that AMR could lead to US$1 trillion in additional healthcare costs by 2050 globally[35].

Downstream treatment failure is one of the least visible but most damaging leakages in the pharmaceutical value chain. It converts a medicine quality issue into repeat healthcare spending for households and the public system. Using India's FY24 domestic pharmaceutical consumption base of INR 2,01,372 crore, even if 2% to 3% of medicine spend results in clinically meaningful treatment failure, the exposed value is INR 4,027 crore to INR 6,041 crores. After accounting for repeat consultations, replacement medicines, diagnostics, prolonged therapy, and hospitalization in severe cases, the annual downstream

burden can conservatively be estimated at INR 5,000 crore to INR 9,000 crore. The larger concern is that without timely recall and recovery, a failed batch or poor-quality product is not removed from the system quickly enough, allowing the same defect to create repeated patient-level and system-level costs[36].

Expert Quote

"Health is fundamental for every person , productivity and growth of the nation. Medicines are central to health care and integral part of sustainable development goals of access to health care for all .

Every medicine manufactured and supplied is intended to improve patient outcomes . Ensuring the integrity of the pharmaceutical supply chain is a shared responsibility across all stakeholders. Counterfeit and falsified medicines are not merely a regulatory concern, they constitute a criminal offence that directly endangers patient safety, undermines trust in healthcare systems, and compromises public health outcomes. Strengthening awareness among patients, healthcare professionals, distributors, and policymakers is essential to prevent such products from entering and circulating within the legitimate supply chain.

At the same time, significant value is lost across the pharmaceutical ecosystem due to inefficient reverse logistics mechanisms especially related to expired medicines and product recalls. These challenges impact supply chain efficiency, increase healthcare costs, and contribute to avoidable wastage of valuable medicines. India has built one of the world's strongest pharmaceutical manufacturing and distribution networks and the next step is to strengthen post-market accountability through improved traceability, recall management, medicine recovery systems, and stakeholder awareness. A more resilient and accountable supply chain will not only enhance patient safety but also reinforce India's position as a trusted global leader in healthcare and pharmaceuticals."

- Amit Talwar, Associate Secretary General,
Indian Pharmaceutical Alliance

Recommendations for Plugging in the Leaks

As highlighted in this report, these leakages may total nearly INR 48,000 crore annually, representing resources lost before medicines deliver their intended therapeutic value. Addressing this issue does not require rebuilding India's pharmaceutical ecosystem. India already has one of the world's largest pharmaceutical manufacturing, procurement, and distribution systems. The next step is to establish the missing reverse pathway.

This report therefore proposes two complementary national policy interventions:

01 **A National Drug Recall Policy**

02 **A National Medicine Buyback / Take-Back Policy**

Together, these interventions would establish a lifecycle approach to medicine management, ensuring medicines remain traceable, recoverable, and accountable at every stage.

The National Drug Recall Policy

The National Drug Recall Policy would target medicines that should not remain in circulation. Substandard, spurious, falsified, contaminated, or otherwise unsafe medicines pose direct risks to patients and healthcare systems. Although India has recall guidelines, the current framework is fragmented and primarily advisory. A robust recall system should establish legally enforceable obligations for manufacturers and supply chain actors, create a centralized recall portal, enable batch-level traceability using QR and barcode technologies, define time-bound retrieval protocols, and support public notifications via pharmacies, hospitals, SMS alerts, and digital health platforms. The goal is clear: if a medicine is identified as unsafe, the system must know its location and retrieve it promptly.

National Drug Recall Policy – Proposed Stakeholder Responsibility Matrix

Stakeholder	Sector	Primary Responsibility	Key Actions
Ministry of Health and Family Welfare	Public	Legislative anchor	Draft and pass enabling legislation, define recall classifications, set statutory timelines, establish compensation framework for public procurement programmes
CDSCO	Public	Enforcement	Create and operate a central recall portal, issue reazcall orders as per classifications, verify recall completion, maintain reports of monetary estimates for every recall
Dept of Pharmaceuticals (DOP)	Public	Policy design and financing	Allocate budget for central recall portal and batch-tracking infrastructure, collaboratively draft the policy with MoHFW, design Extended Producer Responsibility framework, design SOPs for execution
State Drug Controllers	Public	State-level enforcement	Report NSQ data to CDSCO in standardised digital format, implement the SOPs on ground
Pharmaceutical Manufacturers	Private	Compliance	Follow retrieval SOPs, participate in the EPR, maintain and report batch-level distribution records with the SDC
Pharmaceutical Distributors and Wholesalers	Private	Supply Chain	Maintain digital batch inventory, return recalled product to manufacturer, report batch movement data to state drug controller
Pharmaceutical Distributors and Wholesalers	Private	Last mile	Maintain digital batch inventory, return recalled product to manufacturer, report batch movement data to state drug controller
Pharmaceutical Distributors and Wholesalers	Private	Digital recall and reverse logistics	Leverage last-mile delivery networks to support product retrieval at consumer level, notify consumers who purchased recalled medicines, enable in-app medicine return scheduling, transport recalled product to designated collection points
CGHS/NHM/State Procurement Agencies	Public	Compensation Framework	Create policy for compensation under the framework

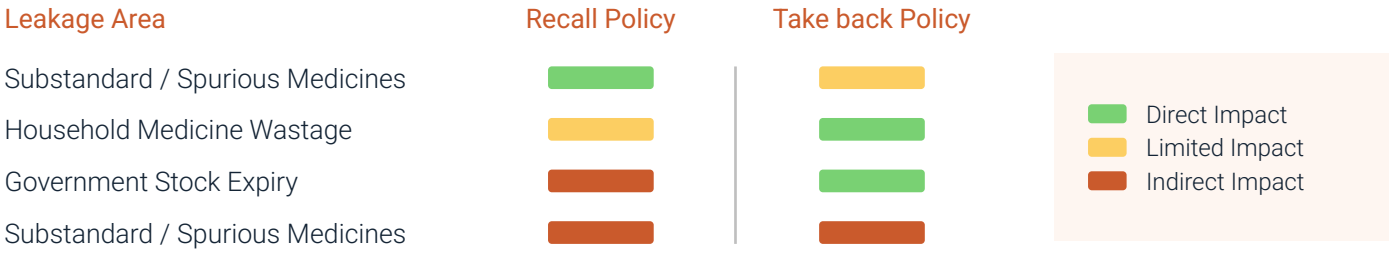
The National Medicine Buyback or Take-Back Policy

The National Medicine Buyback or Take-Back Policy would address medicines that are safe but no longer needed. Unused household medicines, near-expiry inventory, excess public stock, and medicines made redundant by therapy changes are major sources of avoidable wastage. A structured recovery system would allow citizens, pharmacies, hospitals, and public health facilities to return medicines through designated channels. Recovered medicines could then be evaluated for redistribution, supplier return, recall processing, or environmentally safe disposal at approved biomedical waste facilities.

National Medicine Buyback/Take-Back Policy – Proposed Stakeholder Responsibility Matrix

Stakeholder	Sector	Primary Responsibility	Key Actions
Ministry of Health and Family Welfare	Public	Legislative anchor	Draft and pass enabling legislation, policy for unit-dose dispensing for high turnover prescription medicine, establish biomedical waste standards for recovered medicines
CDSCO	Public	Enforcement	Define protocols for evaluating recovered medicines (redistribution vs disposal), approve biomedical waste facilities as authorised disposal partners, maintain database of take-back collection volumes by district
Dept of Pharmaceuticals (DOP)	Public	Policy design and financing	Establish Producer Responsibility Organisation (PRO), policy for collection-based incentive program for Jan Aushadhi Kendras, integrate take-back metrics into PMBJP performance reporting
Pharmaceutical Manufacturers	Private	Compliance	Register with and contribute to PRO, accept near-expiry stock returns from pharmacies, fund safe disposal of returned product, transition to unit-dose packaging where mandated
Jan Aushadhi Kendras	Public	Compliance	Serve as mandatory medicine return points for consumers, transfer collected and segregated stock to district CMSD aggregation hubs
Retail Pharmacies and Hospital Dispensaries	Private	Last mile	Participate in take-back and adopt unit-dose dispensing to reduce structural waste at point of sale
Quick Commerce Platforms (Blinkit, Tata 1mg, PharmEasy, Apollo 24/7)	Private	Reverse logistics	Extend existing delivery networks to support doorstep medicine collection
ASHA Workers & Community Health Volunteers	Public	Rural and last-mile access	Conduct door-to-door collection of unused and expired medicines during routine household visits
NHM / CGHS / State Procurement Agencies	Public	Public procurement reform	Include mandatory take-back clauses in all pharmaceutical procurement tenders
Consumers / Households	Public	Participation	Return unused or expired medicines to Jan Aushadhi Kendras, participating pharmacies, or schedule doorstep collection via quick-commerce platforms

The relationship between these interventions and the identified leakages is straightforward:



The table highlights a key point: neither policy alone resolves the issue. A recall system targets medicines that should not remain in circulation, while a take-back system addresses those no longer needed. Together, they establish the missing reverse pathway in India's pharmaceutical ecosystem.

India already has much of the infrastructure needed to implement this framework. Jan Aushadhi Kendras, district warehouses, Central Medical Store Depots, state procurement agencies, public hospitals, and digital platforms such as e-Aushadhi and DVDMS form a nationwide network that supports medicine recovery, redistribution, and traceability. The opportunity is to integrate these existing assets into a coordinated pharmaceutical recovery system, rather than create new institutions.

India also possesses a unique advantage that few countries have had in building medicine recovery systems: one of the world's largest and fastest-growing quick-commerce and hyperlocal logistics ecosystems.

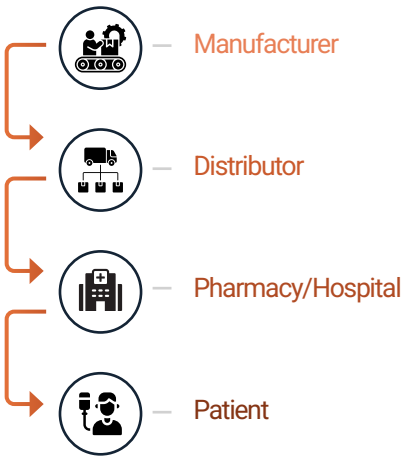
Platforms such as Blinkit, Zepto, Swiggy Instamart, Apollo 24/7, Tata 1mg, and PharmEasy have built extensive last-mile delivery networks that reach millions of households daily. While these platforms currently focus on delivering medicines and healthcare products, their infrastructure can also support medicine recovery.

In the future, citizens could schedule the return of unused, expired, recalled, or excess medicines through the same digital channels they use to order medicines. Quick-commerce partners could collect medicines during regular delivery routes and transport them to designated pharmacies, Jan Aushadhi Kendras, district aggregation centres, or authorized disposal facilities. This approach would significantly reduce barriers to medicine recovery and remove the need to build a new reverse logistics network.

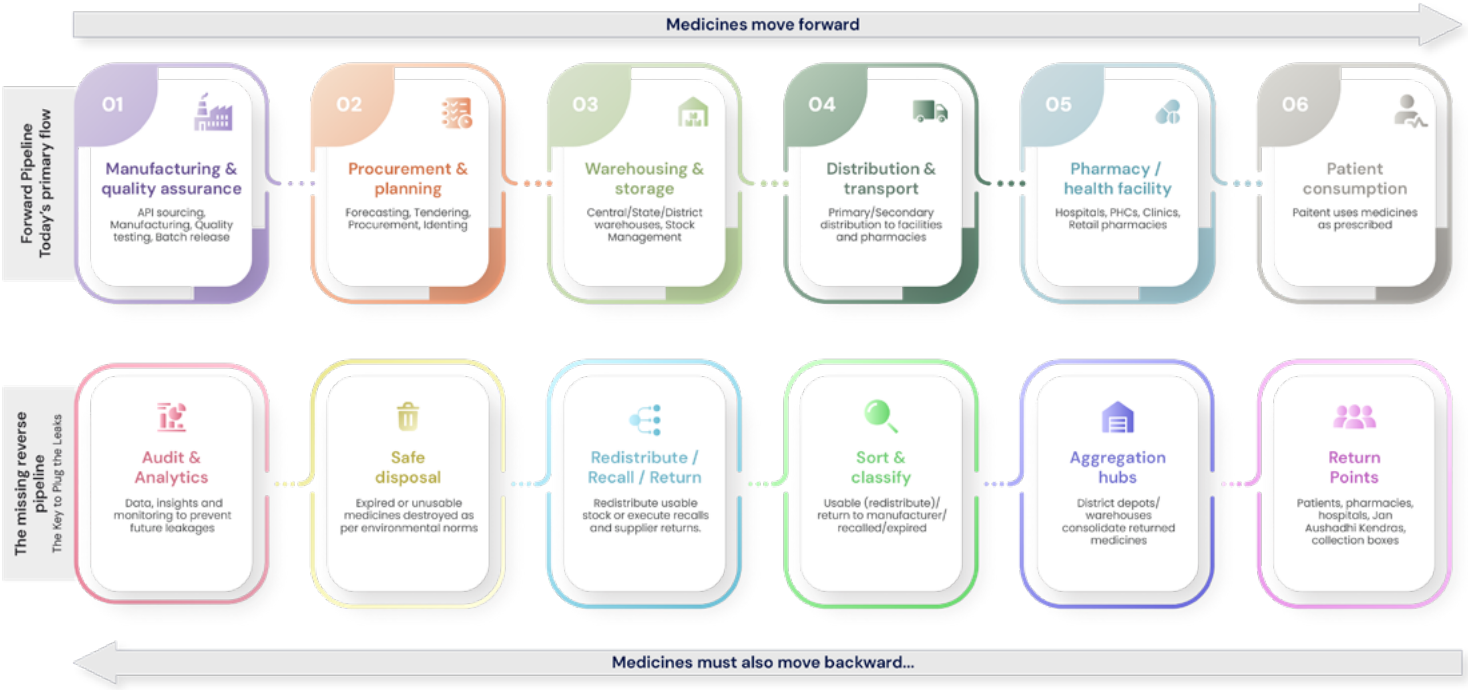
This presents a significant opportunity for India. Most international take-back systems rely on pharmacy-based collection. India can surpass traditional models by combining pharmaceutical accountability with its expanding digital commerce infrastructure. By making medicine recovery as convenient as delivery, India can increase citizen participation in take-back programs and accelerate the shift to a circular pharmaceutical economy.

Ultimately, the goal is not only to reduce wastage, but to transform India's pharmaceutical value chain from a linear supply system to a lifecycle accountability system.

Today, medicines move in one direction:



A leak-free future would introduce the missing reverse pathway:



This reverse pathway is what closes the loop.

India's pharmaceutical success story has historically been built on scale, affordability, and access. The next phase will be defined by accountability, traceability, recovery, and therapeutic outcomes. By combining a National Drug Recall Policy, a National Medicine Buyback or Take-Back Policy, and innovative use of existing logistics and digital infrastructure, India can set a global benchmark for pharmaceutical accountability. The next frontier is becoming the world's most trusted, accountable, and outcome-driven pharmaceutical ecosystem.

Expert Quote

"India has rightfully earned its position as the Pharmacy of the World through manufacturing excellence, affordability, and quality. The next frontier of leadership lies beyond production—in strengthening post-market accountability through traceability, efficient recall systems, medicine recovery, and lifecycle stewardship. A technology-enabled ecosystem that enhances patient safety, reduces wastage, combats counterfeiting, and improves supply-chain visibility will not only protect public health but also reinforce global confidence in Indian pharmaceuticals. The future of pharmaceutical excellence will be measured not merely by medicines manufactured, but by outcomes delivered and accountability maintained throughout the product lifecycle."

- Dr. Dinesh Dua, Past CO Chairman, CII Exports Committee-North, Past Chairman, Pharmexcil, MOC, GOI, Past Chairman, Lifesciences & Innovation & Start-Up Committees, CII North India

Systems that Closed the Loop

Several countries recognize that pharmaceutical governance must encompass the entire lifecycle of medicines, not only their manufacturing and sale. The main argument is that health systems must manage medicines as traceable, recoverable, and accountable products from production to safe disposal. Over the past two decades, many countries have invested in systems that close the loop in pharmaceutical management, making lifecycle oversight a standard for mature health systems.

The United States operates one of the world's most structured medicine recall ecosystems through the US Food and Drug Administration (FDA). The FDA maintains a centralized nationwide recall framework[37] supported by batch traceability, mandatory reporting requirements, and public recall databases. Products identified as defective, contaminated, mislabelled, or therapeutically unsafe can be rapidly traced and withdrawn across states through coordinated supply-chain communication systems. The country also supports large-scale medicine take-back programs, including National Prescription Drug Take Back Days[38] led by the Drug Enforcement Administration (DEA), enabling households to safely return unused medicines instead of discarding them in household waste or sewage systems.

Across Europe, pharmaceutical accountability has evolved into a broader circular governance model. The European Union's Falsified Medicines Directive[39] introduced serialization and barcode-based[40] verification systems that allow medicines to be tracked across the supply chain and authenticated at the point of dispensing. Many European countries also operate pharmacy-based medicine return systems funded through Extended Producer Responsibility (EPR) mechanisms, in which manufacturers help finance safe collection and disposal systems. France's Cyclamed[41] program and Sweden's nationwide pharmacy return systems[42] are often cited as successful examples of consumer-facing pharmaceutical recovery ecosystems with high public participation.

Canada and Australia have similarly implemented structured medicine return programs integrated directly into community pharmacies. Australia's Return Unwanted Medicines (RUM)[43] Program allows citizens to return expired or unused medicines to pharmacies nationwide, reducing environmental contamination and accidental misuse while improving accountability for medicines. These programs recognize that unused medicines are not merely household waste but a public health and environmental risk that requires organized recovery systems.

In several advanced healthcare systems, digital inventory[44] visibility and FEFO inventory management are also widely used to reduce stock expiry across hospitals and public procurement systems. Countries such as the United Kingdom[45] and Singapore[46] have invested heavily in integrated pharmaceutical supply-chain monitoring systems that allow real-time tracking of stock movement, expiry risks, and redistribution opportunities across facilities. This reduces wastage by enabling medicines nearing expiry in one location to be transferred to another location with higher demand before financial loss occurs.

The central principle is clear: successful pharmaceutical governance requires full lifecycle accountability. Leading systems measure success not only by manufacturing capacity or availability, but by how well medicines are managed after entering circulation. The main argument emphasizes a shift from a supply-only mindset to integrated lifecycle management, combining recall systems, traceability, reverse logistics, digital inventory, pharmacy take-back, and producer responsibility under unified governance.

India has achieved global leadership in pharmaceutical manufacturing and affordability. The next step, as the main argument asserts, is for India to implement post-market accountability systems that ensure medicines deliver therapeutic value throughout their lifecycle. As global health systems shift to circularity and outcome-based governance, closing the pharmaceutical loop will be central to public health efficiency and credibility.

What does a leak-free pipeline mean for India

India's pharmaceutical industry transformed global healthcare by making high-quality, affordable medicines available at scale. Yet, India's next healthcare breakthrough hinges on ensuring that these medicines improve health outcomes – maximizing not just quantity, but true therapeutic impact.

A pharmaceutical pipeline free of these losses is central to real health progress – delivering not just more medicines, but better health outcomes for patients and the country.

To achieve this, India must prioritize establishing a comprehensive pharmaceutical accountability system. Key next steps include implementing stronger recall frameworks, digital traceability, medicine take-back programs, real-time inventory visibility, and data-driven procurement. This coordinated approach will create benefits well beyond cost savings.

Establishing this framework will require upfront investment in digital infrastructure, regulatory capacity, and reverse logistics. However, given that even a 25% reduction in estimated annual leakage would recover approximately INR 10,000–12,000 crore per year, the fiscal case for investment is strong.

Detailed costing of implementation including the central recall portal, PRO establishment, and Jan Aushadhi Kendra integration, should form the basis of a subsequent feasibility study. As India's pharmaceutical market expands, a more accountable ecosystem could preserve several lakh crores in economic value, supporting the Viksit Bharat 2047 vision.

But the opportunity is not merely fiscal.

A closed-loop pharmaceutical system would position India as a global leader in both pharmaceutical manufacturing and governance. As countries prioritize traceability, sustainability, circular healthcare, and post-market accountability, India can set a new global benchmark for affordable and accountable medicine systems at scale.

The public health impact could be equally significant. Reducing medicine wastage would improve availability in public facilities. Enhanced recall systems would strengthen patient safety. Lower treatment failure rates could decrease avoidable hospitalizations and antimicrobial resistance. Structured medicine recovery would also reduce environmental contamination from pharmaceutical disposal.

Ultimately, a leak-free system would achieve what matters most – translating scarce healthcare resources into measurable health outcomes, rather than losing value to inefficiency.

However, the cost of inaction will become harder to absorb. As pharmaceutical consumption grows, leakage will increase. Without structural reforms, annual losses could multiply by 2047, turning today's operational inefficiency into a major fiscal and public health burden.

Being the Pharmacy of the World is not enough. India's challenge now is to become the global standard for pharmaceutical trustworthiness, accountability, and measurable health outcomes.

India's true pharmaceutical leadership will be defined by one metric: ensuring every medicine delivers full health value, both at home and for the world.

Authors & Contributors

Nilaya Varma
Managing Director

Vivek Tandon
Vice President

Veda Halve
Asst. Vice President

Shivani Gupta
Manager

Chetan Pant
Manager

Dr. Aneri Kamalakar Chavan
Senior Consultant

Geetanjli Agrawal
Executive Director

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*This figure carries inherent uncertainty and should be treated as an order-of-magnitude estimate;

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