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Drugs in the Indian market: A review

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Abstract:
India supplies affordable medicines globally, yet persistent quality and regulatory failures threaten patient safety and public trust. Major concerns include substandard medicines, irrational fixed-dose combinations, weak adverse-event reporting, fragmented oversight and import-dependent active ingredients. Therefore, it is of interest to examine the scale, causes and regulatory responses associated with these interconnected market challenges. Current measures, including product bans, price controls, QR-based traceability and the pharmacovigilance programme of India, show uneven implementation. Stronger surveillance, coordinated enforcement, domestic manufacturing and innovation are required to secure quality-driven pharmaceutical leadership.

Keywords: Indian pharmaceutical industry, substandard medicines, drug pricing, pharmacovigilance, fixed-dose combinations, regulatory challenges, drug quality

Background:
India is a major global supplier of affordable generic medicines and vaccines, making its pharmaceutical sector central to international health security **[1]**. The country's manufacturing scale has expanded access to essential medicines across low- and middle-income settings **[2]**. However, quality failures, irrational products and uneven regulatory enforcement continue to affect confidence in medicines manufactured and marketed in India **[3]**. Substandard and falsified products can cause treatment failure, toxicity, antimicrobial resistance and avoidable economic loss **[4]**. International alerts involving contaminated paediatric oral medicines have further intensified scrutiny of manufacturing controls and post-market surveillance **[5]**. India's policy response spans bans on irrational fixed-dose combinations, price regulation, pharmacovigilance, traceability measures and incentives for domestic bulk-drug production **[6–8]**. Therefore, it is of interest to evaluate the major drug-market challenges, the effectiveness of existing responses, persistent evidence gaps and priorities for regulatory reform.

Crisis of counterfeit and substandard medicines:
Magnitude and measurement:
Medicine-quality failure is a serious public-health risk, but its prevalence in India remains difficult to quantify because studies use different sampling frames, analytical methods and definitions. A field study in Delhi and Chennai confirmed the presence of substandard products but also showed the limitations of small, location-specific surveys **[9]**. Broader reviews show wide variation in reported prevalence and caution against applying pooled global estimates directly to India without representative national surveillance **[10]**. Consequently, policy should rely on standardized risk-based sampling, accredited laboratory testing and transparent publication of regulatory findings rather than unverified claims.

Pandemic-related amplification:
Counterfeit and substandard medicines remain a major public health challenge in India, driven by regulatory gaps, supply chain vulnerabilities, and inadequate pharmacovigilance **[11].** The COVID-19 pandemic disrupted global supply chains and created exceptional demand for medicines, oxygen-related products and hospital consumables. These conditions enabled falsification, diversion and black-market sale of products such as remdesivir and other widely sought therapies. Evidence from the pandemic indicates that shortages, border restrictions and rapidly changing treatment practices increased opportunities for counterfeiters and weakened routine oversight **[12]**. Emergency preparedness should therefore include protected procurement channels, batch-level authentication and rapid communication between regulators, hospitals, manufacturers and law-enforcement agencies. Strengthening surveillance, regulatory enforcement, technological traceability, and intersectoral collaboration is essential to reduce patient harm and curb antimicrobial resistance.

Online and informal distribution:
Unlicensed online pharmacies and informal sellers widen access to products that may bypass prescription controls, quality assurance and traceable distribution. Digital sales can obscure the identity of the seller, the origin of the product and the conditions under which it was stored. Technology-based authentication, including serialization, scannable codes and interoperable verification databases, can strengthen detection when combined with enforcement and consumer awareness **[13]**. Digital tools alone are insufficient unless suspect products can be reported, investigated and recalled promptly.

Irrational fixed-dose combinations:
Therapeutic rationality:
Fixed-dose combinations (FDCs) can reduce pill burden and improve adherence when their components have compatible indications, doses and pharmacokinetic profiles. In contrast, irrational FDCs may expose patients to unnecessary ingredients, duplicate pharmacological effects, avoidable toxicity and inappropriate antimicrobial use. An assessment of antibiotic FDCs available in India found that more than 90% of evaluated formulations were irrational and many were unapproved or prohibited **[14]**. Rationality assessment should therefore be based on therapeutic need, evidence of efficacy and safety, dose

compatibility and alignment with essential-medicine and antimicrobial-stewardship principles.

Regulatory gaps and product bans:
The historical separation between central approval and state manufacturing licences allowed some combinations to enter the market without adequate central evaluation. Government prohibition of 156 FDCs in August 2024 represented an important corrective action **[6]**. However, market evidence indicates that banned products may continue to circulate when enforcement is delayed, substitutes are introduced or sales channels are not actively monitored **[15]**. Product prohibition should therefore be accompanied by national recall procedures, sales-data surveillance, coordinated inspections and clear accountability across central and state regulators.

Prescriber awareness:
Regulation must be supported by informed prescribing. In a survey of resident doctors, 81% lacked adequate knowledge of the rationality of selected FDCs and fewer than half could identify a banned combination **[16]**. Continuing professional education, hospital formulary review, electronic prescribing alerts and antimicrobial-stewardship oversight can reduce demand for irrational products. Educational interventions should emphasize that an FDC is justified only when the combination offers a clear clinical advantage over separately available components.

Pharmacovigilance: A system in progress
Historical development:
India's current national pharmacovigilance framework began with the launch of the Pharmacovigilance Programme of India (PvPI) in 2010. The Indian Pharmacopoeia Commission subsequently became the National Coordination Centre, supporting adverse drug reaction monitoring, signal detection, training and communication with regulatory authorities **[7]**. The programme has expanded institutional participation and connected Indian safety data with the WHO international monitoring system. This development provides an essential foundation for population-specific evidence on medicine safety.

Persistent reporting barriers:
Despite institutional expansion, spontaneous reporting remains limited by inadequate awareness, uncertainty about causality, fear of blame, workload, lack of feedback and the belief that a single report has little value **[17]**. Indian experience also shows marked variation in reporting activity between institutions and clinical departments **[18]**. Under-reporting delays signal detection and weaken the ability to assess medicines introduced with limited long-term safety data. Pharmacovigilance should therefore be integrated into routine clinical documentation, accreditation standards, professional training and hospital quality systems.

Digital and institutional strengthening:
PvPI has introduced multiple reporting pathways, including forms for healthcare professionals and consumers, web-based processing, mobile tools and helpline-supported reporting. These mechanisms can improve accessibility, but their effectiveness depends on awareness, data quality, timely causality assessment and visible regulatory action **[19]**. Hospitals should designate trained pharmacovigilance personnel, provide regular feedback to reporters and use electronic health records to identify potential safety signals. Direct patient reporting should complement, rather than replace, professional clinical assessment.

Drug pricing: The trade-off between affordability and innovation:
Regulatory architecture:
The National Pharmaceutical Pricing Authority implements the Drugs (Prices Control) Order, 2013 and fixes ceiling prices for scheduled formulations. The framework is intended to improve affordability by linking price control to medicines included in the National List of Essential Medicines **[20]**. Price regulation is particularly important in a health system where medicines constitute a substantial component of household expenditure. Nevertheless, price ceilings must be accompanied by reliable supply, quality assurance and monitoring of market availability.

Impact and unintended consequences:
Evidence on the effect of price control is mixed. A quasi-experimental analysis of antibiotic sales found limited overall growth in utilization after DPCO 2013, although consumption shifted from non-controlled to controlled formulations **[21]**. An interrupted time-series analysis of anticancer medicines similarly showed that lower prices did not automatically produce the expected increase in private-sector utilization **[22]**. These findings indicate that affordability is influenced by prescribing, distribution, awareness, procurement and availability in addition to listed price. Pricing policy should therefore be evaluated using patient access, continuity of supply, quality and health outcomes rather than price reduction alone.

Regulatory fragmentation and quality compliance:
Central-state coordination:
Drug regulation in India involves the Central Drugs Standard Control Organization and State Licensing Authorities, creating a shared system of approvals, inspections and enforcement. Variation in staffing, laboratory capacity and interpretation of standards can produce uneven implementation across states **[23]**. A unified digital licensing platform, common inspection protocols, risk-based audit schedules and mandatory exchange of enforcement data would reduce duplication and regulatory gaps. Clear escalation procedures are also required when a product is marketed across multiple jurisdictions.

International compliance and traceability:
Indian manufacturers supplying regulated export markets are subject to inspections and may receive observations or warning letters when deficiencies are identified. Recurrent findings

related to data integrity, documentation, contamination control and quality systems can damage confidence in the wider sector **[24]**. Mandatory QR or barcode-based identification on selected medicine packs is a constructive traceability measure, provided that the code links to reliable product, batch and manufacturer information **[25]**. Traceability should be integrated with recall systems, wholesaler records and consumer reporting to create an auditable supply chain.

API dependence and supply-chain vulnerability:

Import dependence:

India's finished-formulation strength coexists with substantial dependence on imported active pharmaceutical ingredients, key starting materials and intermediates. Concentrated sourcing creates vulnerability to geopolitical tension, export restrictions, transport disruption and sudden price increases **[1]**. Such shocks can affect domestic availability and international supply because Indian manufacturers serve multiple global markets. Strategic planning should identify high-risk essential APIs and maintain diversified suppliers, quality-qualified alternatives and emergency reserves.

Domestic manufacturing response:

Production-linked incentives and bulk-drug park initiatives aim to rebuild domestic capacity for selected critical materials. These programmes may improve resilience, but sustainable production requires competitive scale, environmental infrastructure, reliable utilities, technical expertise and predictable procurement **[26]**. Policy evaluation should measure not only installed capacity but also commercial output, quality compliance, cost competitiveness and reduction in single-country dependence. Collaboration between government, academia and industry is needed to develop efficient manufacturing processes and higher-value pharmaceutical innovation.

Medicine quality and surveillance:

The available evidence confirms that medicine-quality failures require serious attention, but it does not support simplistic claims about a single national prevalence. Indian field data remain geographically limited, while international reviews show that prevalence estimates are highly sensitive to sampling design and testing methods **[9, 10]**. India needs a continuously updated national post-market surveillance system with statistically defensible sampling, public dashboards and rapid risk communication. Greater transparency would improve accountability while preventing exaggerated or unsupported estimates from shaping policy.

Regulation of fixed-dose combinations:

The FDC problem demonstrates that product bans are necessary but not sufficient. High levels of irrationality among antibiotic combinations reflect weaknesses in evidence review, market entry controls and prescribing demand **[14]**. Enforcement studies show that commercial incentives and established market presence can sustain sales after prohibition **[15]**. Durable reform therefore requires pre-market scrutiny, real-time sales monitoring, coordinated recalls and clinical decision support.

Pharmacovigilance capacity:

PvPI has created a national structure for safety monitoring, yet the clinical reporting culture remains inconsistent. Knowledge gaps, limited feedback and workload-related barriers continue to reduce spontaneous reporting **[17, 18]**. Accessible digital tools can expand participation, but the programme must show that submitted reports lead to signal assessment, communication and regulatory decisions **[19]**. Institutional performance indicators should include report quality, reporting timeliness, signal closure and feedback to patients and professionals.

Pricing and industrial sustainability:

Price regulation remains essential for equitable access, but published analyses show that lower ceiling prices do not automatically increase utilization **[21, 22]**. Availability, prescriber behaviour, distribution and public procurement can modify the effect of price control. A balanced approach should protect patients from excessive prices while monitoring shortages, quality substitution and withdrawal of low-margin products. Incentives for clinically valuable innovation should be transparent and linked to demonstrable therapeutic benefit.

Regulatory coherence and supply resilience:

The recurring themes across medicine quality, FDCs, pharmacovigilance and pricing are fragmented information and uneven enforcement. Stronger central-state alignment, interoperable regulatory databases and risk-based inspections would improve consistency **[23]**. International inspection findings should be used as system-learning opportunities rather than treated as isolated company events **[24]**. At the same time, domestic production programmes must convert policy incentives into reliable, quality-assured API supply **[25]**.

Limitations of the review:

This narrative review may be affected by selection bias and heterogeneity in the available evidence. Several claims are derived from regulatory reports, sales databases or limited regional studies rather than representative national surveys. Rapid changes in notifications, banned-product lists and regulatory programmes may also reduce the currency of individual estimates. Future reviews should use reproducible systematic methods and clearly separate verified regulatory data from media reports and market projections.

Conclusion:

India's pharmaceutical strength is undermined by uneven quality control, irrational products, under-reporting and fragmented regulation. Reform should combine coordinated enforcement, transparent surveillance, rational prescribing, affordable pricing and resilient domestic API production. Long-term global leadership will depend on making quality, safety and innovation measurable priorities across the medicine lifecycle.

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