JETIR.ORG ISSN: 2349-5162 | ESTD Year : 2014 | Monthly Issue
JOURNAL OF EMERGING TECHNOLOGIES AND INNOVATIVE RESEARCH (JETIR)
An International Scholarly Open Access, Peer-reviewed, Refereed Journal

# Regulations of Adulterated, Spurious, and Misbranded Drugs: A Comprehensive Overview

**MOHD IMRAN UZAIR*, ABDUL MANNAN, M. SURESH BABU, MOHAMMED LUQHMAAN, MOHAMMED SOHAIL.**

Department of pharmaceutics, Deccan school of Pharmacy, Aghapura, Hyderabad

**ABSTRACT:**

The global pharmaceutical industry faces significant challenges due to the proliferation of adulterated, spurious, and misbranded drugs, which pose serious threats to public health and safety. This article aims to provide a comprehensive overview of the definitions, classifications, regulatory frameworks, and implications of these substandard pharmaceutical products, with a particular focus on the Indian context. The article discusses the historical evolution of the counterfeit drug crisis, its economic and health impacts, and the legal mechanisms in place to combat it. It elaborates on the distinctions between adulterated, spurious, and misbranded drugs under the Drugs and Cosmetics Act, 1940, and examines the recent amendments introduced through the Jan Vishwas (Amendment of Provisions) Act, 2023. These amendments aim to decriminalize minor violations, rationalize penalties, and promote ease of doing business while maintaining regulatory compliance. The article further explores the types and sources of adulterants, categories of spurious drugs, and common misbranding practices, alongside measures taken by regulatory authorities such as the Central Drugs Standard Control Organization (CDSCO) to enhance surveillance and quality control. It also highlights India's dual role as a major exporter of affordable generics and a country grappling with domestic and international allegations regarding substandard drug exports. By analyzing existing legal provisions, enforcement mechanisms, and recent policy reforms, this review seeks to contribute to the ongoing discourse on strengthening drug regulation, improving traceability, and safeguarding global public health.

**Keywords:** Adulterated, Spurious, Misbranded, Jan Vishwas Act 2023.

## 1. INTRODUCTION:

Since the 1980s, counterfeit medicines have grown from a hidden threat into a global health crisis, costing $200 billion annually and accounting for over 15% of the world's pharmaceutical trade. Low- and middle-income countries are most affected, with up to 30% of drugs suspected to be fake or substandard, compared to less than 1% in wealthier nations. India, the fourth-largest drug producer and a key supplier of affordable generics, plays a dual role—exporting high-quality medicines globally while also facing criticism for substandard products. Weak regulations, inconsistent legal definitions, and limited testing capacities in importing countries exacerbate the issue, leading to treatment failures, drug resistance, and preventable deaths. Addressing this crisis requires global collaboration through stronger regulation, technology-driven traceability, and unified standards to protect public health and preserve trust in medicine.

## 2. ADULTERATED DRUGS

A drug is considered to be adulterated:

(i) if it consists in whole or in part of any filthy, putrid, or decomposed substance.

(ii) if it has been prepared, packed or stored under poor sanitary conditions whereby, it may have been contaminated with filth and rendered injurious to health.

(iii) if container of the drug is composed in whole or in part of any poisonous substance which may render the contents injurious to health.

(iv) if it contains a colour other than one which is prescribed,

### 2.1 Adulteration:

Adulteration refers to the intentional or unintentional replacement of a genuine medicinal substance—typically a crude drug—with another material that mimics its appearance but lacks equivalent chemical or therapeutic value. This practice compromises the efficacy, safety, and authenticity of pharmaceutical products and can arise through various mechanisms. These include the partial or complete substitution of the original ingredient with an inferior alternative, the mixing of extraneous substances due to negligence or oversight,

or deliberate manipulation to mask poor quality. Adulteration not only undermines the intended medicinal effects but also introduces risks of toxicity or adverse reactions, particularly when the substitute material is chemically dissimilar or biologically inert.

**2.2 REGULATORY ASPECTS OF ADULTERATED DRUGS:**

*2.2.1 JAN VISHVAS ACT 2023:*

The Jan Vishwas (Amendment of Provisions) Act, 2023 amended the Drugs and Cosmetics Act, 1940 to decriminalize and rationalize penalties for minor or technical violations, aiming to reduce the burden of stringent criminal liabilities on businesses. Key changes include removing imprisonment as a penalty for certain offenses under the Act and allowing compounding (payment of fines instead of facing prosecution) for violations such as misuse of government analysts' reports (Section 29). These amendments shift the focus from punitive measures to a trust-based governance model, promoting ease of doing business while maintaining regulatory compliance in the pharmaceutical and cosmetics sectors. The Act also aligns with broader efforts to streamline regulatory processes and encourage innovation by reducing legal risks for industries critical to public health and economic growth

**Table-1: Sections, Imprisonments, fines & Amendments of Adulterated Drugs**

| SECTIONS | IMPRESONMENTS | FINES | AMENDMENTS MADE IN JANWISHWAS ACT |
|---|---|---|---|
| **Section 13(1)(a)** | Imprisonment for **3–5 years** + fine | **Compounding allowed**: Fine of **Rs 20,000+** to avoid imprisonment (1–2 years) | Reduced imprisonment Option to compound penalties |
| **Section 27** | Mandatory imprisonment for **minimum 3 years**, extendable to 5 years + fine | **Imprisonment up to 2 years** OR fine of **not less than Rs 10,000** | Removal of mandatory minimum sentence Decriminalization via fine option |
| **IPC Section 275** | Imprisonment for **6 months** OR fine | **Fine of Rs 20,000+** replaces imprisonment | Full decriminalization for minor offenses |
| **General Penalty Adjustment** | N/A | **Fines increased by 10%** across amended provisions | Adjustments to fines to account for inflation |

**3. SPURIOUS DRUGS**

A drug is deemed to be a spurious drug:

(i) if it is imported under a name which belongs to another drug.

(ii) if it is an imitation of or a substitute for another drug or if it resembles another drug in a manner likely to deceive or bears upon it or its label or container the name of another drug.

(iii) if it has been substituted wholely or in part by another drug, substance.

(iv) if it claims to be the product of a manufacturer or company of whom it is not truly a product.

**3.1 Types of Spurious drugs:**

Category A (Spurious and Adulterated Drugs):

Spurious or imitation drug products are drug formulations manufactured concealing the true identity of the product and made to resemble another drug, especially some popular brand, to deceive the buyer and cash on the popularity of original product. The product may or may not contain the active ingredients. Spurious drugs are usually manufactured by unlicensed anti-social elements but sometimes licensed manufacturers may also be involved. The adulterated drugs are those drugs which are found to contain an adulterant/substituted product or contaminated with filth rendering it injurious to health.

Category B (Grossly sub-standard drugs)

Drugs manufactured by licensed manufacturers and reported to have defects of serious nature to affect the quality of the drug. Such defects may arise out of gross negligence or non-conformance to GMPs during manufacture. These defects may broadly be as under:

i. Active ingredient contents below 70% for thermo labile products and below 5 % of the permitted limits for thermo stable products.
ii. Tablets/Capsules failing in disintegration tests wherever prescribed.
iii. Tablets/Capsules failing in dissolution test and active contents foundNless than 70% for thermo labile products and below 5 % of the prescribed limits for thermo stable products.
iv. Liquid preparations showing presence of fungus.

v. Parental preparations failing in sterility, pyrogen/endotoxin test or undue toxicity.
vi. Vaccines failing in potency, sterility, toxicity or moisture content.
vii. Presence of any adulterant which renders the product injurious to health.

Category C (Minor defects)

Drugs manufactured by the licensed manufacturers found not of standard quality because of defects arising out of minor variations in quality. Such defect may arise because of inadequate pre-formulation development studies, lack of in process controls exercised by the manufacturer or unsuitable conditions under which drugs are stored or transported. Examples of some such the defects are as under:

i. Broken or chipped tablets.
ii. Presence of spot/discolouration/uneven coating.
iii. Cracking of emulsions.
iv. Clear liquid preparations showing sedimentation.
v. Change in colour of the formulation.
vi. Slight variation in net content.
vii. Formulations failing in weight variation.
viii. Formulations failing to respond to the colour test.
ix. Isolated cases of presences of foreign matter.
x. Labelling error including nomenclature mistake, Rx, NRx, XRx, Red Line, Schedule H. Caution, Colour etc.

**3.2 SFFC or NSQ drugs in India:**

India, a leading global producer of generic medicines and active pharmaceutical ingredients, faces persistent scrutiny over the quality of its drug exports. Reports suggest that 12–25% of medicines worldwide may be substandard, contaminated, or counterfeit, with India and China often cited as potential sources. According to Patrick Lukulay, Vice President of the US Pharmacopoeial Convention's global health programs, both nations likely play a significant role in this issue. A European Commission report further implicates India, stating that 75% of global cases involving spurious medicines originate there.

Recent investigations were sparked when India and 29 other Asian countries were accused of supplying counterfeit drugs to Nigeria. While India has long been praised for providing affordable, quality medicines to African nations like Uganda and Tanzania, critics allege that substandard antimalarials, antibiotics, and contraceptives have been exported to these regions—claims India and China firmly deny.

*4.2.1 Measures for SFFC or NSQ drugs:*

1. For effective regulatory surveillance throughout the country, Hyderabad and Ahmadabad have upgraded from subzone to full zone while Bangalore, Chandigarh, and Jammu have established as new subzones under the direction of CDSCO.
2. CDSCO publishes monthly a list of drugs, medical devices, and cosmetics that are evaluated and declared as not of standard quality/spurious/adulterated/misbranded.
3. Enhancement of Central Drug Laboratories with new sophisticated testing equipment set up and the creation of a new testing laboratory at Hyderabad.
4. To ensure proper traceability of those manufacturing units, which are situated abroad, from where drugs product is imported in India, a new scheme for regular overseas inspection has been introduced. For instance, two such inspections have formerly done in China.

**3.3 Regulatory Aspects of Spurious drugs:**

*3.3.1 JAN VISHVAS ACT 2023:*

The Jan Vishwas (Amendment of Provisions) Act, 2023 amended the Drugs and Cosmetics Act, 1940 to decriminalize and rationalize penalties for minor or technical violations, aiming to reduce the burden of stringent criminal liabilities on businesses. Key changes include removing imprisonment as a penalty for certain offenses under the Act and allowing compounding (payment of fines instead of facing prosecution) for violations such as misuse of government analysts' reports (Section 29). These amendments shift the focus from punitive measures to a trust-based governance model, promoting ease of doing business while maintaining regulatory compliance in the pharmaceutical and cosmetics sectors. The Act also aligns with broader efforts to streamline regulatory processes and encourage innovation by reducing legal risks for industries critical to public health and economic growth

**Table-2: Offences, Penalties & Amendments of Spurious Drugs**

| OFFENCES | SECTIONS UNDER DRUGS AND COSMETIC ACT | NATURE OF OFFENCE | PENALTIES BEFORE JANWISHWAS ACT | PENALTIES AFTER JANWISHWAS ACT | EXPLANTION |
|---|---|---|---|---|---|
| Manufacture, Sale or Distribution of Spurious Drugs | **Section 9D (1)** | Cognizable, non-Bailable | Imprisonment: Minimum 1 year to 10 years Fine: Minimum ₹10,000 to ₹5 lakh | Imprisonment: Minimum 3 years, extendable to 10 years Fine: Minimum ₹5 lakh, extendable to ₹10 lakh | This section criminalizes the intentional manufacture, sale, distribution, or exports of spurious drugs. Post-amendment, both minimum imprisonment and fine have been significantly increased to act as a deterrent. |
| Repetition of Offence | **Section 9D (2)** | Repeat Offender | Imprisonment: Minimum 3 years to 10 years Fine: Minimum ₹20,000 to ₹10 lakh | Imprisonment: Minimum 6 years, extendable to 10 years Fine: Minimum ₹10 lakh, extendable to ₹20 lakh | If someone has previously been convicted under Section 9D and commits the same offence again, the punishment is enhanced. The amendment raises the bar for repeat offenders. |
| Possession of Spurious Drugs with Intent to Manufacture/Sell | **Section 9D (3)** | Possession with intent | Imprisonment: Minimum 1 year to 10 years Fine: Minimum ₹10,000 to ₹5 lakh | Imprisonment: Minimum 3 years, extendable to 10 years Fine: Minimum ₹5 lakh, extendable to ₹10 lakh | This covers possession of spurious drugs or materials used in making them, when done with intent to commit an offence under Section 9D. |
| Use of False Name or Description of Drug | **Section 9D (4)** | Misrepresentation | Imprisonment: Minimum 1 year to 10 years Fine: Minimum ₹10,000 to ₹5 lakh | Imprisonment: Minimum 3 years, extendable to 10 years Fine: Minimum ₹5 lakh, extendable to ₹10 lakh | Using a false name or description of a drug that may lead people to believe it is genuine is also treated as spurious. Penalty remains unchanged post-amendment. |
| Punishment for Abetment of Offence under Section 9D | **Section 9G** | Abetment | Imprisonment: Minimum 1 year to 10 years Fine: Minimum ₹10,000 to ₹5 lakh | Imprisonment: Minimum 3 years, extendable to 10 years Fine: Minimum ₹5 | Anyone who abets the commission of any offence under Section 9D shall be punished with |

| | | | | | |
|---|---|---|---|---|---|
| | | | | lakh, extendable to ₹10 lakh | the same penalty as if they had committed the offence themselves. |

## 5. MISBRANDED DRUGS

A drug is considered as a misbranded drug:

(i) if it is not labeled in the prescribed manner.

(ii) if it is so coloured, coated, powdered or polished that damage is concealed or it is made to appear of better or greater therapeutic value than it really is.

(iii) if the label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or gives misleading information.

### 4.1 Regulatory Aspects of Misbranded Drugs:

*5.1.1 JAN VISHVAS ACT 2023:*

The Jan Vishwas (Amendment of Provisions) Act, 2023 amended the Drugs and Cosmetics Act, 1940 to decriminalize and rationalize penalties for minor or technical violations, aiming to reduce the burden of stringent criminal liabilities on businesses. Key changes include removing imprisonment as a penalty for certain offenses under the Act and allowing compounding (payment of fines instead of facing prosecution) for violations such as misuse of government analysts' reports (Section 29). These amendments shift the focus from punitive measures to a trust-based governance model, promoting ease of doing business while maintaining regulatory compliance in the pharmaceutical and cosmetics sectors. The Act also aligns with broader efforts to streamline regulatory processes and encourage innovation by reducing legal risks for industries critical to public health and economic growth.

**Table-3: Sections & Amendments of Misbranded Drugs**

| SECTIONS | PRE JAN VISHWAS ACT | POST JAN VISHWAS ACT | KEY CHANGES |
|---|---|---|---|
| **Section 17** | Defined misbranded drugs (e.g., false labelling, concealment of defects). | Retained definition but decriminalized first-time offenses. | Focus shifted to penalties over prosecution. |
| **Section 18** | Prohibited manufacture/sale of misbranded drugs with imprisonment up to 2 years and fines. | Replaced imprisonment with **monetary penalties** (first-time: ₹10,000; repeat: escalated fines) | Decriminalization of minor violations. |
| **Section 27(d)** | Punished NSQ (Not of Standard Quality) and misbranded drugs with up to **2 years' imprisonment**. | Amended to impose **fines up to ₹5 lakh** (compounding mechanism) instead of imprisonment for first-time offenders. | Financial penalties prioritized. |
| **Section 32B** | Not applicable (introduced by Jan Vishwas Act). | Introduced **compounding of offenses** (fines instead of prosecution) for minor violations like misbranding. | Rationalization of penalties. |
| **Repeat Offenses** | No specific provision for escalated penalties. | **Enhanced fines** (e.g., 10% annual increase) for repeat violations; imprisonment retained only for non-payment of fines. | Deterrence through financial escalation. |
| **Ayurvedic/Siddha/Unani Drugs (Section 33E)** | Misbranding penalties included imprisonment and fines. | Fines applied for labelling/composition violations; imprisonment removed for first-time cases. | Harmonized penalties across drug categories. |

**CONCLUSION:**

A comprehensive overview of the challenges posed by adulterated, spurious, and misbranded drugs within the Indian pharmaceutical sector. It highlights how these substandard products threaten public health, contribute to drug resistance, and undermine global trust in medicine supply chains. India's dual role as a leading exporter of affordable generics and a country facing allegations of poor quality control is discussed, emphasizing the need for robust regulatory mechanisms. The study identifies key legal frameworks such as the Drugs and Cosmetics Act, 1940, and recent amendments introduced through the Jan Vishwas Act 2023, which aim to decriminalize minor violations, rationalize penalties, and promote ease of doing business while safeguarding quality standards. Regulatory authorities like CDSCO have taken measures including enhanced surveillance, upgraded testing infrastructure, and international collaborations to ensure traceability and compliance. The findings underscore the importance of strengthened enforcement, technology-driven solutions, and global cooperation in combating counterfeit drugs. To address these issues effectively, continuous policy reforms, investment in regulatory infrastructure, and stakeholder collaboration are essential. Ultimately, ensuring drug authenticity and safety requires a multi-faceted approach that balances stringent oversight with industry-friendly practices to protect public health and maintain India's credibility in the global pharmaceutical market.

**REFERENCES:**


1. Ankit Raj, Tushar Yadav, Swapnil Patil, Atin Kalra, Satish Sardana, Pradip Nirbhavane, Counterfeit medicine: a major public health concern and effective remedies for combatting the crisis, Discover Pharmaceutical Sciences, Published on: Mar 07, 2025. https://doi.org/10.1007/s44395-025-00004-6
2. Vikram Rameshrao Khangan, Rupali Hemant Tiple, The Challenge of Counterfeit Drugs in Indian Market: A Comprehensive Review, Indian Journal of Pharmacy Practice., 2025; 18(4):352-361.
3. Richard Wilder, Sam Halabi, Lawrence O. Gostin, Global and national actions to prevent trade in substandard and adulterated medicines, Global Public Health, Published on: FEB 20, 2025. https://doi.org/10.1371/journal.pgph.0004024
4. Anonna Dutt (September 29, 2024) Random checks finds paracetamol, other drugs 'not of standard quality': What should you do?. The Hindustan Express, https://indianexpress.com/article/explained/explained-health/random-checks-finds-not-of-standard-quality-drugs-in-market-heres-all-you-need-to-know-9592135/
5. Rajesh, S., Dhamotharan, J., Kumar, P. S., Babu, M. A., Jagadeesan, M., & Reddy, K. T. K. (2022). Eradication of spurious adulterated and under standard quality drugs, a regulatory pertaining in Indian regulatory system. International Journal of Health Sciences, 6(S8), 1611–1627. https://doi.org/10.53730/ijhs.v6nS8.11647
6. Dr. Mayuri Prem, Singh Kshatriya, Dr. Satej Banne, A Critical Analysis on Adultration and Substitution of Crude Drugs Vol.-24 (July-December, 2023), Peer Reviewed ĀMNĀYIKĪ, ISSN No. 2277-4270, UGC Care Listed Journal, https://www.researchgate.net/publication/377019068
7. Singh A. Combating Counterfeit and Substandard Medicines in India: Legal Framework and he Way Ahead. Current Research Journal of Social Sciences and Humanities. 2023 6(1). DOI: http://dx.doi.org/10.12944/CRJSSH.6.1.08
8. Pooja Agrawal, Virendra Kushwaha, Alpana Sahu and Pradeep Kumar, SPURIOUS DRUGS (A BRIEF REVIEW), WORLD JOURNAL OF PHARMACEUTICAL RESEARCH, volume 12, Issue 2, 564-574. publication at: https://www.researchgate.net/publication/373768245
9. Dooguri Vijaya Lakshmi, K. Chaitanya Prasad, Dr. K. Nagasree, Dr. Y. Sirisha, Current trends in regulatory actions against misbranding and adulteration, International Journal of Allied Medical Sciences and Clinical Research (IJAMSCR) IJAMSCR |Vol.11 | Issue 4 | Oct - Dec -2023 www.ijamscr.com
10. Suryaprakash Singh, Priyanka Gupta, A Comprehensive Study on Counterfeit Medicine and its prevention in India through its Regulatory Approach, International Journal of Drug Regulatory Affairs. 2022; 10(2): 9-13. Available online on 15 Jun, 2022 at https://ijdra.com/index.php/journal
11. Ozawa, S., et al. Access to medicines through health systems in low-and middle-income countries. 2019, Oxford University Press [Internet]. 2019 Dec[cited 2022 Jan 19]; iii1-iii3 Available from: https://academic.oup.com/heapol/article/34/Supplement_3/iii1/5670624
12. Doni Prakash Kumar, Umasankar .K, Alagusundaram .M, Jayachandra Reddy .P, Current Trends in Regulatory Authority Actions against Misbranded and Adulterated Drugs, International Journal of Advance Research, Ideas and Innovations in Technology. SSN: 2454-132X Impact factor: 4.295 (Volume3, Issue3), Available online at www.ijariit.com
13. Yadav, S. and G. Rawal. Counterfeit drugs: problem of developing and developed countries. Int J Pharmceut Chem Anal [Internet]. 2015 Mar[cited 2022 Jan 25]; 2(1): 6-50 Available from: https://scholar.google.com/scholar?hl=en&as_sdt=0%2C5&q=Yadav%2C+S.+and+G.+Rawal%2C+Counterfeit+drugs%3A+problem+of+developing+and+developed+countries.+Int+J+Pharmceut+Chem+Anal%2C&btnG=#
14. A. N. KHAN AND R. K. KHAR, Current Scenario of Spurious and Substandard Medicines in India: A Systematic Review, Indian Journal of Pharmaceutical Sciences · March 2015, publication at: https://www.researchgate.net/publication/273464064
15. Nehal A. Shah, Bhagya M. Sattigeri, Nirav N. Patel, Haresh A. Desai, Counterfeit drugs in India: significance and impact on pharmacovigilance, International Journal of Research in Medical Sciences Shah NA et al. Int J Res Med Sci. 2015 Sep;3(9):2156-2160 www.msjonline.org
16. Verma, S., R. Kumar, and P. Philip. The business of counterfeit drugs in India: A critical evaluation. International Journal of Management and International Business Studies, [Internet]. 2014 Nov[cited 2022 Jan15]; 4(2) : 141-148 Available from: https://www.researchgate.net/publication/340581356_The_Business_of_Counterfeit_Drugs_in_India_A_Critical_Evaluation

17. Buowari, O., Fake and counterfeit drug: a review. Afrimedic Journal [Internet]. 2013 Mar [cited 2022 Mar 15];3(2):1-4. Available from: https://www.ajol.info/index.php/afrij/article/view/86573
18. Bansal, D., et al. Anti-counterfeit technologies: a pharmaceutical industry perspective. Scientia pharmaceutical [Internet]. 2012 Oct [cited 2022 Mar 09]; 81(1):1-14. Available from: https://www.mdpi.com/2218-0532/81/1/1
19. Ambroise-Thomas P. The tragedy caused by fake antimalarial drugs. Mediterranean journal of haematology and infectious diseases. 2012;4(1)
20. Shukla N, Sangal T. Generic drug industry in India: the counterfeit spin. Journal of Intellectual Property Rights. 2009;14(3):236-40.
21. A "Spurious" Definition: Need to Amend the Drug and Cosmetics Act 2015 [cited 2015]. Available from: http://spicyip.com/2009/08/spurious-definition-need-to-amend-drug.html.
22. Adulteration—Vikaspedia
23. Kumar DP, Umasankar K, Alagusundaram M, JayachandraReddy P. Current trends in regulatory authority actions against misbranded and adulterated drugs, semantic scholar; 2017
24. World Bank. India. 2011. Available from: http://www.data.worldbank.org/country/india [Last cited on 2013 Mar 14].