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WHEN MEDICINE TURNS POISON: INDIA'S LEGAL BLIND SPOTS ON SUBSTANDARD DRUGS

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ABSTRACT

The pharmaceutical sector has emerged as one of the most critical pillars of public health and the economy in recent times, especially after the COVID-19 pandemic, which has also made people more aware of its importance in delivering safe medicines and life-saving vaccines. This article traces the legislative history of the Drugs and Cosmetics Act, 1940, first introduced in British India, through various amendments and reports by the expert committees on the effectiveness of its provisions. Over the decades, various committees and policy documents, from the Hathi Committee to the Mashelkar Committee, have highlighted systemic deficiencies and have recommended stronger oversight, culminating in amendments and reforms aimed at ensuring drug safety and quality. Despite these efforts, various challenges such as inconsistent enforcement across states, inadequate recall mechanisms, and weak regulatory autonomy have persisted. It critically assesses the need for legal frameworks that ensure both procedural efficiency and accountability in drug quality regulation to protect public health. Further, a comparative analysis of the law related to substandard drugs between developed nations like the USA and European countries, and India points to the systemic deficiencies within India's drug regulatory apparatus and underscores the pressing need for enhanced regulatory measures to strengthen this framework and to maintain Good Manufacturing Practices. The article also analyses possible implications of the amendments to the Drugs and Cosmetics Act, 1940 introduced through the Jan Vishwas (Amendment of Provisions) Act, 2023 which came into effect on 31st December 2024.Furthermore, this article addresses the Union Health Ministry's recently proposed changesto the New Drugs and Clinical Trial Rules, 2019, focusing on streamlining regulatory approvals by allowing

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pharmaceutical companies to conduct certain bioavailability and bioequivalence (BA/BE) studies.

Keywords:*Drugs and Cosmetics Act (1940), Substandard drugs, Good Manufacturing Practices,Jan Vishwas (Amendment of Provisions) Act (2023), New Drugs and Clinical Trial Rules (2019).*

INTRODUCTION

The Drugs and Cosmetics Act, 1940 classifies offences related to drugs into various categories. In the Indian context, the focus has been on spurious drugs which has overshadowed the concerning prevalence of substandard drugs. This necessitates a deeper understanding of the subtle difference between these various categories of drugs.

"Spurious drugs", or fake drugs, are manufactured with the sole intention of monetary profit and to deceive the customer by selling them as genuine. In contrast, substandard drugs are manufactured by licensed manufacturers in their own names but without the observing the Good Manufacturing Practices (GMPs). This non-compliance leads to proliferation of products that are either lower in potency compared to what is claimed on the label or contain toxic substances. Contrary to what many might imagine, the prevalence of substandard drugs is a much more serious problem than spurious drugs facing India.[3]

The existing legal system classifies drug related offences with respect to quality and packaging of drugs into four categories: "misbranded drugs", "spurious drugs", "adulterated drugs", and drugs that fail to meet the standards of quality as outlined in the Drugs & Cosmetics Act, 1940. Generally, "misbranded" means drugs that are mislabelled or have false or misleading representations of ingredients and falsely represent therapeutic value. "Spurious drugs" include false representations as to the identity of the manufacturer or to the nature or quantity of the ingredients. "Adulterated drugs" are those which contain filthy or decomposed substances, or which have been prepared in insanitary conditions. However, there is no definition of "substandard" drugs under the Act; Section 18(a)(1) only prohibits the manufacture of a drug which does not comply with the standards of quality. This lack of

[3]Dinesh S. Thakur, 'Enforcement measures under the Drugs & Cosmetics Act, 1940 – Part 13: What's in the name?', (*DineshThakur*, 10May 2016) <https://dineshthakur.com/2016/05/10/enforcement-measures-under-the-drugs-cosmetics-act-1940-part-13-whats-in-the-name/> accessed 20 July 2025.

articulation arguably plays down the sizeable concern regarding poor-quality drugs in India's drug supply chain.

LEGISLATIVE HISTORY

The Drugs and Cosmetics Act,1940 has been in force for 87 years now but there still remains a lacuna in its implementation. This has also been partly because of the non-uniform application throughout states and the lax attitude of the regulatory authorities.

The Act was first introduced in 1937 in British India on the recommendations of the Drugs Enquiry Committee with the object of regulating the import of drugs into British India. In order to bring about uniformity and ensure that the measure was comprehensive, the Government of India encouraged Provincial Legislatures to pass resolutions so as to empower the Central Legislature to pass an Act to regulate manufacture, distribution and import of drugs, a subject under the Provincial Legislative List. Thus, the Drugs and Cosmetics Bill, passed by the Central Legislative Assembly, received the assent of the Governor General on April 10, 1940.[4] The Drugs and Cosmetics Act, 1940 established the Central Drugs Standard Control Organisation to perform the functions allocated by the Central Government. The CDSCO is headed by the Drugs Controller General India and is attached to the office of the Director General of Health Services under the Ministry of Health and Family Welfare.

However, the need for an independent body with a higher degree of autonomy was felt in order to ensure a robust drug regulation system in the country. The Drug Policy of 1978, 1986 and 1994 envisaged the establishment of the National Drug Authority to ensure the enforcement of appropriate quality standards for drugs and Good Manufacturing Practices. It would regulate all matters relating to introduction and rational use of drugs, in particular, the registration of new formulations and rationalization of existing formulations. It would also be assigned the specific function of quality control and quality assurance with a predominantly inspectoral role to ensure adherence to standards, specifications and manufacturing capabilities and practices.[5]

[4]Department Of Medical, 'Health & Family Welfare Govt. Of Rajasthan, Drugs And Cosmetics Act, 1940' (2011) <https://rajswasthya.nic.in/Drug%20Website%2021.01.11/DC%20Act,%20About%201.pdf> accessed 17 November 2024.

[5]Lily Srivastava, *Law & Medicine* (2nd edn, Universal Law Publishing Co. Pvt. Ltd. 2013) 358-359.

In 2002 the Union Ministry of Health and Family Welfare expressed its intention to "set up a world class Central Drug Standard Control Organization (CDSCO) by modernizing, restructuring and reforming the existing system and establish an effective network of drugs standards enforcements administrations in the States with the CDSCO as a nodal center, to ensure high standards of quality, safety and efficacy of drugs and pharmaceuticals", as laid down in the Pharmaceutical Policy Document.[6]

The Pharmaceutical Industry became a prominent contributor to the nation's economy. India occupied the fourth position in the world in terms of volume of production and witnessed a remarkable transformation from being an importer in the 1950s to a prominent exporter on the international front. With the ever-increasing diversity and quantity of drugs developing, the need to check the quality of drugs became imperative. Following this trend, stricter quality control systems were adopted by most countries to clean their markets of substandard and counterfeit drugs.

To address these issues relating to drug quality, key institutions such as the Supreme Court of India, the National Human Rights Commission, and the Standing Committee of Parliament demanded improvement in the drug regulatory framework of India. Other previous recommendations, including that from the Hathi Committee Report of 1975, had also recommended a National Drug Authority that would monitor the regulatory practice. Since the enactment of the Drugs and Cosmetics Act of 1940, it had never been reviewed in depth until 2003. Still, the rules of this Act were amended from time to time according to the changing needs. The above concern about substandard drugs again established the need for a strong and integrated policy for regulating the quality and standard of drugs in the country. Therefore, in 2003 the Government of India, in a renewed effort to curb the menace of substandard drugs in its entirety, set up an Expert Committee headed by Dr. R.A. Mashelkar. The Committee was tasked with recommending amendments to the Drugs and Cosmetics Act, 1940, proposing changes in judicial procedures relating to offences committed under this Act, and suggesting a structure for the Drug Regulatory System in the country to make it robust.

[6]Ministry of Chemicals and Fertilizers, 'Pharmaceutical Policy 2002' (*Department Of Pharmaceuticals*, 15 February 2002)<https://archive.pib.gov.in/release02/lyr2002/rfeb2002/15022002/r1502200212.html> accessed 23 July 2025.

The Committee concluded that the existing infrastructure at the State and the Centre were not adequate and thus, proposed to strengthen the existing authorities under the new status of Central Drug Administration.[7] This authority was to be patterned after the model used by the U.S. Food and Drug Administration. The CDA was conceived as an independent mechanism responsible for the overhaul of India's drug regulatory framework. The CDA was supposed to bring uniformity in drug licensing, improve the level of safety in pharmaceutical use and medical devices, and ensure quality in such drugs. However, the drug regime across states was not uniform and thus, the inconsistency of policies and regulations under each state complicated issues regarding enforcement. The need to correct such disparities culminated in the formation of the CDA, on the recommendations of the Mashelkar Committee.

Dr. R.K. Srivastava, director-general health services, Government of India, told Times of India that CDA would be constituted as per the guidelines of the Drug and Cosmetic Act (Amended Rules), 2007 to bring uniformity in the regulation of production, sale, import and use of drugs and medical instruments in the country.[8] The CDA shall be headed by one chairman and three to five members appointed by the Central government with strict qualification criteria for their selection process. Thus, these reforms including the creation of a Central Drug Authority represented a step toward ensuring a more effective and more uniform drug regulatory system within India.

However, these reforms were still not effective. Consequently, The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act, 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs.

A report by the Parliamentary Standing Committee of India on Health & Family Welfare in 2012 did a sharp critique on the drug regulatory framework prevalent in the country, which focused on the functioning of CDSCO. The report concluded that CDSCO ought to be granted greater autonomy to enable effective discharge of its functions. It revealed how, despite absence of strong clinical evidence, some drugs were approved by the DCGI of India, which led to sale of several “new drugs” in India not sanctioned in other well-regulated international markets. It involved off-label drug use, such as an anti-allergy drug marketed

[7]Ministry of Health and Family Welfare, Government of India, Report of the Expert Committee on A Comprehensive Examination of Drug Regulatory Issues, Including the Problem of Spurious Drugs < https://ruralindiaonline.org/static/pdfjs/viewer.html?file=/media/documents/Report_of_the_Expert_Committee_on_a_Comprehensive_Examination_of_Drug_Regulato_fBOOBvk.pdf > accessed 15 June 2025.

[8]Lily Srivastava, *Law & Medicine* (2nd edn, Universal Law Publishing Co. Pvt. Ltd. 2013) 368.

for the purpose of appetite stimulating among children and a drug to treat breast cancer being sanctioned for infertility in women.[9]

The report dwelled on issues such as lack of guidelines for recalling drugs, inconsistent standards for drug storage, and similar brand names for different drugs. These had also been raised in landmark Supreme Court cases such as ***Swantraj& Ors vs State of Maharashtra (1974)***[10] on standards for drug storage and ***Cadila Healthcare Limited vs Cadila Pharmaceuticals Limited (2001)***[11] on similar brand names.

These weaknesses compelled the Ministry of Health to change the way things were going, but their actions only managed to appear superficial, compelling the committee to publish another sharp report criticizing them for lacking real reforms. This led to the formation of different committees to examine issues related to the regulatory system. Many committees' recommendations were ignored or not implemented effectively; however, centralization of drug regulation legislation was attempted but it went cold. Still the government did address a few issues with Fixed Dose Combinations, that is, drugs with two or more active ingredients combined. These measures consisted of filing criminal cases against bureaucratic officials and pharmaceutical firms through the Prevention of Corruption Act, 1988 for allegedly conspiring together to gain unauthorized drug clearances. The health ministry also used Section 26A of the Drugs and Cosmetics Act, 1940 in invoking a ban on 344 FDCs, whereupon this was taken all the way to the courtroom. Finally, after a long legal battle, the Ministry banned 328 FDCs in 2018 and another 80 in 2019.[12]

While the report's legacy endures, it remains imperative for India to reform its drug regulatory system, reflecting continuing problems in enforcing strict standards of drug safety and efficacy nationwide.

JUDICIAL LIMITATIONS IN ENSURING DRUG QUALITYSTANDARDS

Substandard drugs are a major problem and no country in the world is immune to this issue. Therefore, ensuring the quality of drug to protect the public against substandard medicines is

[9]Standing Committee on Health and Welfare, Lok Sabha, Fifty Ninth Report, Report OnThe Functioning OfThe Central Drugs Standard Control Organisation (CDSCO) (2012).
[10]*Swantraj vs State of Maharashtra* AIR 1974 SC 517.
[11]*Cadila Health Care Ltd. v. Cadila Pharmaceuticals Ltd.* (2001) 5 SCC 73.
[12]Dinesh S. Thakur and Prashant Reddy T., *The Truth Pill: The Myth Of Drug Regulation In India* (Simon & Schuster IN 2022)171-172.

the responsibility of each country. The effective response to substandard drugs relies on three main components- drug regulation, surveillance and law enforcement.[13] Thus, the reasons for proliferation of substandard drugs in India cannot be attributed solely to failure of legislative intent but also to lack of judicial enforcement. Inadequate and ineffective implementation of the existing laws to control the drug quality limits their impact, preventing the legislative intent from becoming a reality.

Indian cases dealing with substandard drugs suffer from prolonged judicial proceedings. The cases of Alfred Berg & Co. and Olcare Laboratories highlight this issue, unveiling the challenges faced and the limitations of judiciary's role in enforcing legislations related to substandard drugs. In August 2013, drug samples labelled as Glipizide, manufactured by Alfred Berg & Co. Pvt Ltd, were tested by governmental analysts at the Drug Testing Laboratory in Chennai. The government analysts alleged the presence of Glibenclamide instead of Glipizide, which, if used can lead to increase in possibility of hypoglycemia as it takes more time to be metabolised by human body. A criminal complaint was filed in December 2014, accusing the company of violating Good Manufacturing Practices (GMP). However, as of March 2022, the case did not proceed to trial[14], underscoring the inefficiency of the Indian judiciary in even initiating trials and allowing such companies to remain unharmed.

Similarly, there are various instances where judges have pronounced quite absurd decisions. In the criminal complaint filed in August 2009 against Olcare Laboratories, the drug inspectors of Maharashtra found only 25.69mg of Azithromycin instead of the 200mg advertised and declared it to be "Not of Standard Quality" (NSQ). The accused proprietor of Olcare Laboratories along with the manufacturing chemist and analytical chemist pleaded guilty after a prolonged seven-year legal process. Azithromycin is used to treat various life-threatening infections and without enough dosage the possibility of a patient to die increases. However, despite such adverse effect on human life, the court sentenced the offender to "simple imprisonment till the rising of the court" along with a meagre penalty of ₹70,000.[15]

[13]Gillian J. Buckley & Lawrence O. Gostin, *Countering the Problem of Falsified and Substandard Drugs* (Washington (DC): National Academies Press (US) 2013).
[14]Dinesh S. Thakur and Prashant Reddy T., *The Truth Pill: The Myth Of Drug Regulation In India* (Simon & Schuster IN 2022).
[15]ibid 25-26.

Even in instances where it is evident that an NSQ drug poses a significant risk to public health, Indian courts have demonstrated a tendency towards leniency in their judgments. A notable case is that of Tamman Titoe Pharma Pvt Ltd, filed by the Tamil Nadu Drug Control Department in 2019. The company was charged after its drug vials reportedly failed both the assay test and the bacterial endotoxin test[16]- high concentrations of endotoxin can lead to serious complications such as disseminated intravascular coagulation, endotoxin shock, and adult respiratory distress syndrome.[17] However, yet again, the sentence imposed by the XV Metropolitan Magistrate, Georgetown, Chennai, surprisingly merely consisted of "simple imprisonment till the rising of the court" alongside a nominal fine of ₹50,000.[18]

In the case of ***M.Y. Ahmed v. Drugs Inspector***[19], the petitioner sought to quash the proceedings against him based on allegations that he manufactured and sold a drug, Bismuth Trioxide (CBS-120 Tablets), that was found to be of "not of standard quality." While the Drugs Inspector's report indicated that the drugs were of "not of standard quality," the court did not adjudicate on this issue due to the procedural lapse in appointment of the Drug Inspector, rendering the process of taking sample and filing a complaint as illegal. This highlights the issue that courts may focus on procedural flaws rather than the substantive issues of drug quality and public safety. The procedural inefficiency overshadowed the need for ensuring the quality of the drugs manufactured which may lead to a lack of accountability on part of the manufacturers if such reports are correct. The Court should have also discussed the findings of the report to determine their accuracy, ensuring not just the correct application of legal procedure but also the protection of public health interests. This case emphasises the need for clearer legal frameworks that address both procedural and substantive concerns in drug regulation.

A common link between these incidents is the inordinate judicial delay that allows the offenders to get away with it and, in the process, has fostered an environment where the quality of drugs is compromised for financial motives. The leniency of the Indian courts not only undermines the deterrent effect of existing laws, but also raises questions regarding the effectiveness the regulatory regime in safeguarding public health. This ultimately defeats the

[16]ibid 27.
[17]Maud B. Gorbet & Michael V. Sefton, 'Review: Biomaterial-Associated Thrombosis: Roles of Coagulation Factors, Complement, Platelets and Leukocytes' [2016] The Biomaterials: Silver Jubilee Compendium 219.
[18]Dinesh S. Thakur and Prashant Reddy T., *The Truth Pill: The Myth Of Drug Regulation In India* (Simon & Schuster IN 2022) 27.
[19]*M.Y. Ahmed v. Drugs Inspector* 2019 SCC OnLine Mad 5806.

very purpose of the drug-related legislation and thus completely exposes vulnerable populations to life-threatening situations. Reinforcing judicial accountability through expedited trials and imposition of severe punishments is necessary to curb the menace of substandard drugs and to gradually restore people's faith in the country's pharmaceutical sector.

COMPARATIVE ANALYSIS

Union Finance and Corporate Affairs Minister Nirmala Sitharaman hailed India as the "Pharmacy of the World", owing to its high and efficient production of "global standard medicine" at affordable costs.[20] However, the increasing instances of substandard drugs in India, coupled with weak legislation as well as the lack of enforcement of such laws by judiciary, suggest otherwise.

The approach by the Central Drugs Standard Control Organization in managing substandard drugs remains limited, in contrast to the transparency and detailed information provided by the U.S. Food and Drug Administration and the European Medicines Agency. Both the USFDA and the EMA publish comprehensive and detailed reviews for each new drug application, covering a range of technical assessments including medical, chemistry, pharmacology, statistical, and microbiology reviews. The EMA publishes European Public Assessment Reports (EPARs), which include detailed explanations of the scientific bases for its drug approval decisions. These agencies go a step further by releasing all communications between regulators and the pharmaceutical companies, offering insights into the entire review process, rationale for approvals, and even the proprietary name and labeling choices.[21]

The European Drug Prevention Quality Standards, developed through the joint efforts of EMCDDA and the Prevention Standards Partnership, provide the first European framework on how to conduct high quality drug prevention. The EMCDDA has contributed greatly to the advancement of drug prevention in Europe. Its publications and tools, such as the Prevention and Evaluation Resource Kit, the guidelines for the evaluation of drug prevention and the Exchange on Drug Demand Reduction Action database have increased awareness of

[20]Rakhi Bose, 'India Takes Pride In Being 'Pharmacy Of The World' But Cough Syrup, Eye Drop Deaths Tell A Different Story', (*Outlook*, 13 February 2023) <https://www.outlookindia.com/national/india-takes-pride-in-being-pharmacy-of-the-world-but-concerns-over-eye-drops-and-syrups-risk-denting-the-image-news-261679> accessed 20 July 2025.

[21]Dinesh S. Thakur and Prashant Reddy T., *The Truth Pill: The Myth Of Drug Regulation In India* (Simon & Schuster IN 2022).

the need for expert level quality standards for drug prevention.[22] These standards emphasise setting high-quality benchmarks, self-reflection, and continuous development, which are largely absent in India's approach, which tends to focus more on regulatory enforcement and compliance rather than holistic prevention. They prioritise continuous professional development, self-assessment, and quality benchmarks, encouraging professionals to reflect on their practices actively. In India, where drug regulation can be reactive, adopting a self-reflective approach could shift the focus toward proactive prevention and quality assurance. However, these guidelines may experience resistance in India as integrating a punitive approach with a preventive framework may create confusion among stakeholders about the primary objectives of drug regulation.

The concept of drug recall is crucial for ensuring public safety. According to the US Food & Drug Administration, "*A drug recall is the most effective way to protect the public from a defective or potentially harmful product. A recall is a voluntary action taken by a company to remove a defective drug product from the market or warn patients and consumers about a potential risk.*"[23] The FDA classifies drug recalls based on the level of hazard to patients in order of decreasing severity.[24] A total of 15,710 medication recalls were launched during 2012-2023, 1,524 of which were classified as class I recalls, 12,679 as class II recalls and 1,507 as class III recalls initiated by pharmaceutical companies.[25] The FDA has the authority regarding drug recall but it is somewhat limited. As also provided by the definition by FDA, drug recall is a voluntary action, where the FDA can request the manufacturers to voluntarily recall their drugs. However, the FDA can invoke statutory power under the Food, Drug and Cosmetic Act, 1940 to compel the manufacturer to recall.[26]

[22]European Union Drugs Agency, 'European drug prevention quality standards' (European Union Drugs Agency, 1 December 2011) <https://www.euda.europa.eu/publications/manuals/prevention-standards_en.> accessed 19 July 2025.
[23]U.S. Food & Drug Administration, 'Drug Recalls' (*U.S. Food & Drug Administration*, 16 October 2024) <https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls.> accessed 15 July 2025.
[24]ibid.
[25]Ravi Patel, Aksha Vhora et al., 'A Retrospective Regulatory Analysis of FDA Recalls carried out by Pharmaceutical Companies from 2012 to 2023' [2024] Drug Discovery Today 29.
[26]Tyler Natof & Mark V. Pellegrini, 'Food and Drug Administration Recalls' (*Nat'l Library of Medicine*, 1 May 2023) <https://www.ncbi.nlm.nih.gov/books/NBK570589/#article-131541.r3.> accessed 19 July 2025.

Since 1976, there has been deliberation on mandatory recall law for substandard drugs.[27] Even the 59th Report of the PSC expressed concern over the lack of an effective drug recall mechanism.[28] In 2017, Central Drugs Standard Control Organisation reformulated guidelines on recall of drugs and classified them into three categories similar to those of the FDA, and introduced statutory recall, which can be initiated in response to the directions or mandates by the Drug Regulatory Authorities.[29] These guidelines were reviewed again by the office of the DCGI in July 2024[30], however, it is to be noted that the DCGI lacks the power to make rules that are binding and have the force of law. This limitation means that while the DCGI can issue guidelines intended to enhance drug safety and efficacy, these guidelines do not carry the same weight as regulations enacted through the legislative process. Thus, drug recalls in India largely remain voluntary, emphasising the urgent need for a robust enforcement mechanism to ensure their effectiveness.

RECENT DEVELOPMENTS

The Jan Vishwas (Amendment of Provisions) Bill, 2023 was introduced in Lok Sabha on 22nd December 2022.[31] The Bill aims to decriminalise minor offences spread across 42 Acts and 183 provisions, including the Drugs and Cosmetics Act, 1940. The amendments introduced by the Jan Vishwas Act came into force on December 31, 2024, and modified Sections 29, 30(2), and 32B (1) of the Drugs and Cosmetics Act, 1940. The amendment increases the penalty for using a Government Analyst's report in drug or cosmetic advertising by substituting the previous fine limit of INR 5,000 with a penalty of up to INR 1,00,000. It also modifies the penalties for repeat offences under Section 29 of the Act. Previously, a second conviction could result in imprisonment up to two years, a fine of at least INR 10,000,

[27]Dinesh S. Thakur and Prashant Reddy T., 'Explained | Why does India not have a law to recall bad drugs from the market?'*The Hindu* (India, 6 May 2023) <https://www.thehindu.com/sci-tech/health/explained-mandatory-recall-failed-medicines-law-cdsco/article66815213.ece> accessed 23 July 2025.

[28]Standing Committee on Health and Welfare (n 7).

[29]Central Drugs Standard Control Organisation, Guidelines on Recall and Rapid Alert System for Drugs (Including Biologicals & Vaccines) Version 2017<https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/biologicals/4GuidelineRecalRapidAlert.pdf> accessed 23 July 2025.

[30]Central Drugs Standard Control Organisation, Guidelines on Recall and Rapid Alert System for Drugs (Including Biologicals & Vaccines) Version 2024<https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/biologicals/Guidelinerapid24.pdf> accessed 23 July 2025.

[31]Ministry Of Commerce & Industry, 'Lok Sabha passes Jan Vishwas (Amendment of Provisions) Bill, 2023' (*Press Information Bureau*, 27 July 2023) <https://pib.gov.in/PressReleasePage.aspx?PRID=1943393> accessed 23 July 2025.

or both. The Jan Vishwas Act replaces this with a minimum fine of INR 5,00,000, removing imprisonment as a penalty and emphasising financial repercussions for repeat violations. The compoundable offences under Section 32B (1) now include clauses (d) of Section 27 and (ii) of Section 27A. Thus, penalties for manufacturing or selling drugs in violation of the Act under Section 27 (d) which provided a mandate of imprisonment of not less than one year but which may be extended up to two years, and with a minimum fine of INR 20,000, can be reduced by the courts to payment of fine as directed by the Central or the State government.

The Act aims to promote ease of doing business in India which will help in boosting India's reputation on the international front and also compete in the global market. However, the recent deaths of dozens of children in two countries, Gambia and Uzbekistan brought India international shame as these deaths were linked to cough syrups manufactured in India. Thus, it is important to realise that if manufacturers are allowed to scot-free after committing these offences, the goal of the Act is contradicted if India faces international criticism.

Recently the Union Health Ministry has proposed significant changes to the New Drugs and Clinical Trial Rules, 2019 to promote innovation and ease of business in the pharmaceutical sector. The proposed amendments were published in the Gazette of India on 28th August, 2025 and aim to streamline approvals by allowing companies to conduct certain bioavailability/ bioequivalence (BA/BE) studies and manufacture drugs for these trials without seeking prior licenses, requiring only a notification to the CDSCO.[32] This relaxation would apply to oral formulations already approved in highly regulated markets such as the U.S., EU, U.K., Japan, Australia, and Canada.[33]

The proposals also allow manufacturing of unapproved drugs for such trials under the notification process, though beta-lactam antibiotics and products with live microorganisms are excluded. Additionally, the regulatory approval timeline has been halved from 90 to 45 days. These reforms are expected to cut license applications by 50%[34], accelerate drug development, and strengthen India's position as both a global pharmaceutical hub and an

[32]Ministry of Health and Family Welfare, 'Union Health Ministry to Amend New Drugs and Clinical Trials Rules, 2019 for Streamlining Test Licence and BA/BE Study Applications' (*Press Information Bureau*, 3 September 2025) <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2163255> accessed 4 September 2025.

[33]Anonna Dutt, 'Govt. plans easing of clinical trial rules to attract global pharma, faster approvals likely' *The Indian Express* (New Delhi, 3 September 2025)<https://indianexpress.com/article/india/govt-plans-easing-clinical-trial-rules-global-pharma-10228251/> accessed at 4 September 2025.

[34]Ministry of Health and Family Welfare (n 30).

emerging center for innovation. According to The Indian Express editorial, while such nimble regulation can boost pharmaceutical innovation and reduce delays, concerns remain about safety, particularly with complex therapies involving genetic or immune modification.[35]

CONCLUSION

In conclusion, the Drugs and Cosmetics Act, 1940 lays a basic framework for regulating drug standards in India but faces challenges in the face of modern demands concerning drug safety and efficacy. Widespread prevalence of substandard drugs in the Indian market spells critical deficiencies in the system of regulation as well as the judiciary. Efforts at strengthening drug regulation, such as creation of CDSCO and numerous amendment acts, show an intent on the part of the government to set high quality standards, however, the segmented nature of the enforcement mechanism, judicial delay, and inefficient procedures attached to their functioning dilute the effectiveness of deterrent action. What adds to this dismal scenario are the frequently internationally reported instances related to Indian drugs. For India to retain its position as the "Pharmacy of the World", it needs to transition from enforcement to proactive quality assurance and transparency. This decriminalization by the newly enacted Jan Vishwas (Amendment of Provisions) Act, 2023 shows a trend toward the balancing act between the growth of industries and stringent quality control measures. This amendment is expected to increase the safety quotient of drugs; help maintain public health and ensure India's good reputation in the pharmaceutical industry around the world.

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