Comprehensive Analysis of Blacklisted and Banned Medicines in India: Regulatory Framework, Key Cases, and Public Health Implications

Executive Summary

India's pharmaceutical market, a global leader in volume, operates under a complex regulatory framework primarily governed by the Central Drugs Standard Control Organisation (CDSCO) and the Drugs and Cosmetics Act, 1940, and Rules, 1945. This report delves into the critical aspects of drug prohibition and manufacturer blacklisting, vital for ensuring public health and maintaining drug quality. The report highlights that drug bans are primarily driven by concerns over safety, efficacy, and therapeutic irrationality, particularly prevalent in Fixed Dose Combinations (FDCs). While the CDSCO possesses statutory powers under Section 26A of the Drugs and Cosmetics Act, 1940, to prohibit drugs, these decisions frequently face protracted legal challenges from the pharmaceutical industry. Furthermore, manufacturers are increasingly being blacklisted or facing license suspensions for producing "Not of Standard Quality" (NSQ) drugs, reflecting a push for stricter enforcement. However, systemic challenges such as fragmented regulatory authority, resource limitations, and the absence of a mandatory drug recall mechanism continue to impede optimal oversight. The dynamic interplay between regulatory intent, judicial scrutiny, and industry practices underscores the ongoing evolution of India's drug regulatory landscape. Effective enforcement and a robust, transparent system are paramount to safeguard patient well-being and uphold India's reputation as a reliable pharmaceutical producer.

1. Introduction: Defining Banned and Blacklisted Medicines in India

The regulation of pharmaceutical products in India is a critical function aimed at safeguarding public health. Understanding the distinctions between "banned" and "blacklisted" medicines and manufacturers is fundamental to appreciating the regulatory landscape. These terms, while related to non-compliance or safety concerns, refer to distinct regulatory actions and their implications for market availability and industry operations.

1.1. Clarifying Terminology: "Banned" vs. "Blacklisted"

Banned medicines are pharmaceutical products whose manufacture, sale, or distribution for human use has been officially prohibited by the Central Government. This prohibition is typically enacted through gazette notifications, rendering the drug no longer legally available in the market. The primary reasons for such bans are concerns over safety, efficacy, or therapeutic irrationality, often following recommendations from expert bodies like the Drugs Technical Advisory Board (DTAB).[1] For instance, numerous Fixed Dose Combinations (FDCs) and individual drugs like Rofecoxib and Nimesulide (for pediatric use) have been officially prohibited due to these concerns.

In contrast, blacklisted or debarred manufacturers refer to pharmaceutical companies or individuals whose licenses have been suspended, cancelled, or who have been debarred from participating in certain activities, such as procurement or clinical trials. This action is usually taken due to non-compliance with quality standards, ethical violations, or the manufacturing of substandard or spurious drugs. While a blacklisted manufacturer's entire product portfolio might not be banned, their operational capacity or market access is severely restricted.[5] Examples include companies like Jackson Laboratories and Zee Laboratories, which have faced debarment by various state medical procurement bodies for producing "Not of Standard Quality" (NSQ) drugs.

1.2. The Central Drugs Standard Control Organisation (CDSCO): India's Apex Regulatory Body

The Central Drugs Standard Control Organisation (CDSCO) serves as India's National Regulatory Authority (NRA) for cosmetics, pharmaceuticals, and medical devices. Headquartered in New Delhi, this organization operates under the Directorate General of Health Services, which is part of the Ministry of Health and Family Welfare, Government of India. The core mandate of the CDSCO is to ensure the safety, efficacy, and quality of all medical products that are manufactured, imported, and distributed across the nation.[3]

The responsibilities vested in the CDSCO are extensive and multifaceted, encompassing a broad spectrum of regulatory activities. These include the approval of new drugs and the oversight of clinical trials, establishing and maintaining standards for drugs, and controlling the quality of imported pharmaceutical products. The organization also plays a crucial role in coordinating the activities of State Drug Control Organizations, providing expert advice to ensure uniform implementation of regulations. Furthermore, the CDSCO is responsible for granting licenses for specialized critical drugs such as blood and blood products, intravenous fluids, and vaccines. A key function involves

banning drugs and cosmetics that are identified as posing a threat to public safety. The CDSCO is also tasked with proposing and implementing amendments to the Drugs & Cosmetics Act and its associated Rules, conducting testing of new drugs, and performing ongoing oversight and market surveillance to monitor product quality and compliance.[3] To enhance transparency and efficiency in its operations, the CDSCO leverages digital platforms such as SUGAM and the National Single Window System (NSWS) for various licensing, registration, and application tracking processes.[3]

The regulatory scope of the CDSCO has undergone a significant expansion over time. Initially focused primarily on chemical compounds, the definition of a "drug" within the Drugs and Cosmetics Act, 1940, has evolved to include a wider array of substances, diagnostic tools, and medical devices. This broadening mandate is evident in the government's stated intention to bring all medical devices, including implants and contraceptives, under the purview of CDSCO's review.[13] This adaptation reflects a proactive response to advancements in healthcare technology and a heightened awareness of the diverse products impacting public health. However, this expanded jurisdiction inherently introduces greater complexity into regulatory processes, demanding specialized expertise within CDSCO, as indicated by the presence of a dedicated "Medical Device & Diagnostics" division.[13] The ongoing challenge for the regulatory body lies in ensuring consistent and effective oversight across such a wide and continuously evolving product landscape, particularly when resource limitations might affect comprehensive enforcement.

Another critical aspect of India's drug control system is the intricate interplay between central authority and state-level implementation. While the CDSCO functions as the national regulatory body, setting overarching policies and approving new drugs, the day-to-day enforcement, including the issuance of manufacturing and sales licenses, is significantly decentralized to state drug control authorities.[3] The CDSCO is responsible for coordinating the activities of these State Drug Control Organisations and is jointly responsible for granting licenses for certain specialized categories of critical drugs.[18] However, this dual regulatory structure, despite its intent to ensure broad coverage, often leads to fragmentation, inconsistencies, and overlapping jurisdictions.[19] This can create opportunities for "regulatory arbitrage," where manufacturers might exploit differences in enforcement stringency or interpretation across various states. The effectiveness of this system is further challenged by a reported lack of transparency and accountability, coupled with inadequate resources at both central and state levels.[19] These factors can collectively create loopholes that allow substandard or unapproved drugs to persist in the market, posing a risk to public health. The observation that companies are sometimes blacklisted by medical procurement bodies of state governments, rather than through a unified national debarment list, further underscores this persistent fragmentation in enforcement.[5]

2. Legal and Regulatory Framework for Drug Control in India

The legal and regulatory architecture governing drugs and cosmetics in India is robust, designed to ensure product safety, efficacy, and quality. This framework is primarily anchored by foundational legislation and continuously evolving provisions that empower the Central Drugs Standard Control Organisation (CDSCO) to enforce stringent controls.

2.1. The Drugs and Cosmetics Act, 1940 and Rules, 1945: Foundations of Drug Regulation

The Drugs and Cosmetics Act, 1940, stands as the cornerstone legislation in India, meticulously regulating the import, manufacture, distribution, and sale of drugs and cosmetics. The paramount objective of this Act is to guarantee that all such products available in the country are safe for consumption, effective in their intended use, and conform to established quality standards.[13] Complementing the Act, the Drugs Rules, 1945, provide a detailed operational framework, outlining provisions for the classification of drugs under various schedules and offering comprehensive guidelines for their storage, sale, display, and prescription.[3]

Since its enactment, the Drugs and Cosmetics Act has undergone several significant amendments to adapt to evolving challenges and enhance regulatory oversight. A notable amendment, the Drugs & Cosmetics (Amendment) Act 2008, introduced more stringent penalties for the manufacture of spurious and adulterated drugs, elevating certain offenses to cognizable and non-bailable categories. This amendment also made it mandatory for applicants to submit results of bioequivalence studies for certain oral dosage forms and stipulated joint inspections by Central Government and State Government Drugs Inspectors prior to the grant of manufacturing licenses.[8] These legislative enhancements reflect a concerted effort to strengthen enforcement mechanisms and reinforce quality assurance throughout the pharmaceutical supply chain.

The Act provides precise definitions that underpin regulatory actions. It broadly defines "drug" to encompass not only traditional medicines but also diagnostic substances and medical devices. Furthermore, it explicitly addresses "misbranding," which occurs when a drug claims more therapeutic value than it actually possesses, and delineates provisions against "fake and adulterated drugs." The Act also mandates the printing of ingredient details on product labels, ensuring transparency for consumers and healthcare professionals.[17]

2.2. Powers of Prohibition: Section 26A and Other Relevant Provisions

The Central Government's authority to prohibit drugs is primarily enshrined in specific sections of the Drugs and Cosmetics Act, 1940. Section 26A is a pivotal provision, empowering the Central Government to regulate or restrict the manufacture, sale, or distribution of any drug or cosmetic if such action is deemed necessary or expedient in the public interest. This power is typically invoked when a drug is found to pose a risk to human beings or lacks adequate therapeutic justification.[4] Its frequent application in banning Fixed Dose Combinations (FDCs) underscores its central role in drug prohibition.

Complementing Section 26A, Section 10A specifically grants the Central Government the authority to prohibit the import of certain drugs or cosmetics into the country. This provision has been utilized to prevent the entry of substances deemed unsafe or illicit, such as Methaqualone and Chloral Hydrate.[4] While these sections establish broad prohibitive powers, the regulatory framework also accommodates specific needs. For instance, Rule 33, pertaining to the "Form 11 License," allows for a nuanced approach. This license permits the import of small quantities of otherwise banned drugs solely for the purposes of examination, testing, or analysis, thereby facilitating research, quality control, and forensic investigations without allowing commercial circulation.[29]

2.3. Ensuring Quality: Good Manufacturing Practices (GMP) and Standards

The CDSCO's regulatory framework places a strong emphasis on maintaining stringent quality standards and ensuring compliance with Good Manufacturing Practices (GMPs) for all pharmaceutical products. This commitment extends to regular inspections of manufacturing premises to verify adherence to these critical quality benchmarks.[9]

In collaboration with State Drugs Controllers, the CDSCO conducts risk-based inspections of manufacturing facilities. The findings from these inspections can lead to a range of enforcement actions, including the issuance of show cause notices, orders to stop production, and the suspension or cancellation of manufacturing licenses. These actions are implemented by State Licensing Authorities, guided by CDSCO's coordination and established guidelines.[9] A significant recent development in this area is the amendment to the Drugs Rules 1945 in December 2023, which revised Schedule M. This Schedule outlines the Good Manufacturing Practices and specifies requirements for premises, plant, and equipment for pharmaceutical products. The revised Schedule M became effective for large manufacturers in June 2024, with a phased implementation extending the timeline for smaller manufacturers until December 2025.[9] This ongoing revision highlights a continuous effort to elevate manufacturing quality standards across the industry.

The frequent banning of drugs that have been available in the market for decades, particularly Fixed Dose Combinations (FDCs), indicates a historical pattern of regulatory oversight or a reactive rather than consistently proactive approach. The fact that many "irrational" and "unsafe" FDCs were widely sold for years before being prohibited, with some even noted by the Delhi High Court as being in the market since 1988, points to systemic weaknesses in initial approval processes or post-market surveillance.[24] The widespread availability of irrational FDCs in India has been a subject of international discussion for over a decade.[24] This reactive approach to banning, while necessary to address immediate public safety concerns, often leads to market instability and protracted legal disputes, as evidenced by the extensive legal battles with manufacturers following such prohibitions.[24] This situation underscores a fundamental challenge in balancing pharmaceutical innovation, market access, and public safety within the regulatory framework, where past ambiguities are now being addressed, often through judicial intervention.

India's drug regulatory system faces a complex dual challenge: combating deliberate criminal activity, such as the manufacture of spurious and adulterated drugs, while simultaneously ensuring consistent quality from legitimate manufacturers who may produce substandard drugs. Regulatory guidelines differentiate these categories, with Category A (spurious and adulterated drugs) warranting stringent penalties, including potential life imprisonment and substantial fines, and immediate police assistance.[8] In contrast, Category B (grossly substandard drugs) and Category C (minor defects) from licensed manufacturers are often attributed to negligence, non-compliance with Good Manufacturing Practices (GMPs), inadequate formulation studies, or improper storage.[8] The proposal for immediate

license suspension for "Not of Standard Quality" (NSQ) drugs, as recommended by the Drugs Technical Advisory Board (DTAB), highlights this tension. While regulators prioritize public safety, industry groups have voiced concerns, arguing that NSQ incidents are often due to technical lapses rather than intentional wrongdoing.[10] Furthermore, the reliability of initial NSQ assessments by state laboratories has been questioned, with some samples declared NSQ by state labs later found to be of standard quality by the appellate Central Drug Laboratory (CDL) Kolkata.[10] This disparity suggests a critical need for standardization and quality assurance within the drug testing infrastructure itself to ensure fair and accurate assessments. This distinction between intentional fraud and quality control lapses is crucial for developing effective policy, as different types of violations necessitate tailored enforcement strategies and resource allocation.

3. Categories and Key Examples of Prohibited Medicines

The landscape of banned and blacklisted medicines in India primarily features Fixed Dose Combinations (FDCs) and individual drugs that have been identified as posing significant risks or lacking therapeutic justification. Regulatory actions against these categories reflect an evolving understanding of drug safety and efficacy.

3.1. Fixed Dose Combinations (FDCs): A Primary Focus of Bans

Fixed Dose Combinations (FDCs) are pharmaceutical formulations that incorporate two or more active pharmaceutical ingredients (APIs) into a single dosage unit, typically in a predetermined fixed ratio. While FDCs are often intended to enhance patient adherence by simplifying treatment regimens and potentially offering synergistic therapeutic effects, a substantial number of these combinations in India have been identified as "irrational" or "unsafe".[23]

The primary reasons for the prohibition of FDCs are multifaceted:

Irrationality and Lack of Therapeutic Justification: The most prevalent reason for banning FDCs stems from the absence of robust scientific evidence or clear therapeutic justification for combining specific ingredients. Expert committees and the Drugs Technical Advisory Board (DTAB) have consistently concluded that many FDCs lack therapeutic justification for their combined ingredients and may pose risks to human health.[23]
Increased Side Effects and Health Risks: The combination of drugs in an irrational FDC can lead to diminished therapeutic benefits or, more critically, an altered and potentially harmful safety profile compared to the individual components. Specific concerns include the promotion of antibiotic resistance, particularly when irrational antibiotic FDCs are used, and the risk of adverse reactions such as arrhythmia, tacypnea, hypotension, or severe hypersensitivity reactions.[24]
Misuse and Over-medication: The convenience of a single FDC pill can inadvertently lead to unnecessary exposure to multiple drugs. This can potentially mask symptoms, delay accurate diagnosis, or contribute to the development of drug resistance, particularly in the context of antibiotics.[32]

India has seen several significant waves of FDC bans:

2016 Ban: The Central Government initially prohibited 344 FDCs under Section 26A of the Drugs and Cosmetics Act, 1940. This large-scale ban faced considerable legal challenges from pharmaceutical manufacturers.[26]
2018 Ban: Following directives from the Supreme Court and a subsequent re-examination by the DTAB, the Ministry of Health and Family Welfare prohibited 328 FDCs. The Board found no therapeutic justification for these combinations and identified potential risks to human beings. Additionally, six FDCs were restricted subject to specific conditions based on their therapeutic justification.[24]
Recent Bans (2023-2024): The government continues to ban FDCs, with 14 FDCs prohibited in June 2023 and a further 156 FDCs in August 2024. These recent prohibitions have also been challenged in various High Courts, which have, in some instances, issued interim orders allowing the sale of existing stock in the distribution network.[23]

3.2. Individual Drugs Banned for Safety and Efficacy Concerns

Beyond FDCs, several individual drugs have been banned in India due to specific safety and efficacy concerns that emerged from post-market surveillance and scientific re-evaluation.

Rofecoxib: This painkiller was banned due to compelling evidence linking its prolonged, high-dosage use to an increased risk of heart attacks and strokes. Merck, its original manufacturer, voluntarily withdrew Rofecoxib

(marketed as Vioxx) globally in 2004 following disclosures that information regarding these cardiovascular risks had been withheld from doctors and patients for over five years.[1]

Nimesulide (for pediatric use): Nimesulide formulations were prohibited for use in children below 12 years of age, effective March 2011. This ban was instituted due to its strong association with acute hepatitis, severe liver injury, and the potential for acute liver failure and even death in pediatric patients. Despite this restriction, Nimesulide remains available for adult use in India.[1]

Sibutramine: This anti-obesity drug was banned following a global survey that linked its use to an increased risk of cardiovascular disease and strokes. As Sibutramine was not considered a life-saving drug, its potential risks were deemed to significantly outweigh its benefits for weight loss, leading to its prohibition.[1]

Dextropropoxyphene: The ban on Dextropropoxyphene was prompted by its implication in numerous overdose-related deaths, including suicides. Concerns also arose regarding its adverse impact on cardiovascular electrophysiology, specifically QTc interval prolongation, even within therapeutic dose ranges. Furthermore, questions were raised about its overall utility as an analgesic, particularly when compared to safer alternatives.[4]

Other notable individual drugs and specific formulations that have been prohibited include Amidopyrine, Phenacetin, Nialamide, Methaqualone, Methapyriline, Practolol, Penicillin skin/eye ointment, liquid oral preparations of Tetracycline/Oxytetracyline/Demeclocycline, Chloral hydrate, Dover's powder, Chloroform exceeding 0.5% in pharmaceutical preparations, Mepacrine HCl (specifically for female sterilization or contraception), Fenfluramine, Dexfenfluramine, Terfenadine, Astemizole, Phenformin, Cisapride, Rimonabant, Phenyl Propanolamine, and Human Placenta Extract (for topical application in wound healing and injection for pelvic inflammatory diseases). Additionally, the use of Colistin has been prohibited for food-producing animals, and Ketoprofen/Aceclofenac have been banned for veterinary use. Restrictions have also been placed on Oxytocin due to concerns about its misuse. Many FDCs, such as combinations of vitamins with tranquilizers or analgesics, H2 receptor antagonists with antacids (except approved combinations), anthelmintics with cathartics, bronchodilators with antitussives or antihistamines, and estrogens/progestins exceeding certain dosage limits, have also been prohibited.[1]

Table 1: Selected List of Banned Drugs/Fixed Dose Combinations (FDCs) with Primary Reasons and Dates of Prohibition

Drug/FDC Name	Primary Reason for Ban	Key Regulatory Action	Date of Notification/Ban (Approx.)	Relevant Section of Act/Rule
Amidopyrine	Irrational Combination/Safety Concerns	Prohibited	Sep 1983	Section 26A, GSR. NO. 578(E)
Phenacetin	Safety Concerns	Prohibited	Sep 1983	Section 26A, GSR. NO. 578(E)
Nimesulide (for children <12 years)	Hepatotoxicity/Acute Liver Injury	Prohibited (Pediatric Use)	Mar 2011	Section 26A, GSR. 82(E)
Rofecoxib	Increased Cardiovascular Risk (Heart attack, Stroke)	Prohibited	Dec 2004	Section 26A, GSR. 810(E)

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Sibutramine	Increased Cardiovascular Risk (Heart attack, Stroke)	Prohibited	Feb 2011	Section 26A, GSR. 82(E)
Dextropropoxyphene	Overdose-related deaths, Cardiac Electrophysiology Impact	Prohibited/Suspended	May 2013	Section 26A, GSR. 332(E)
Methaqualone	Safety Concerns	Prohibited	Jan 1984	Section 26A, GSR. 49(E)
Human Placenta Extract (topical/injection)	Lack of Therapeutic Justification/Safety Concerns	Prohibited	May 2011	Section 26A, GSR. 418(E)
Fixed Dose Combinations (344 FDCs)	Lack of Therapeutic Justification/Risk to Humans	Prohibited	Mar 2016	Section 26A
Fixed Dose Combinations (328 FDCs)	Lack of Therapeutic Justification/Risk to Humans	Prohibited	Sep 2018	Section 26A
Fixed Dose Combinations (14 FDCs)	Lack of Therapeutic Justification/Risk to Humans	Prohibited	Jun 2023	Section 26A
Fixed Dose Combinations (156 FDCs)	Irrational Combinations	Prohibited	Aug 2024	Section 26A
Colistin (for food producing animals)	Antimicrobial Resistance Mitigation	Prohibited	Jul 2019	Section 26A, S.O. 2607(E)
Oxytocin (Import)	Misuse/Safety Concerns	Prohibited	Apr 2018	Section 10A, GSR. 390(E)
Oxytocin (Manufacture/Sale/Distribution)	Misuse/Safety Concerns	Restricted/Prohibited	Apr 2018	Section 26A, GSR. 411(E)

The extensive number of Fixed Dose Combinations (FDCs) that have been prohibited, with 344 in 2016, 328 in 2018, 14 in 2023, and 156 in 2024, points to a pervasive issue within the Indian pharmaceutical market.[23] These prohibitions are consistently justified by the absence of therapeutic justification and the potential for risk to human beings.[23] A significant concern arises from the fact that many of these FDCs had been available in the market for decades, with some noted by the Delhi High Court as having been present since 1988.[30] An expert perspective highlights that the argument of long-term use is not scientifically sound, emphasizing that "the absence of evidence of harm is not evidence of absence of harm".[30] This suggests a critical gap in historical pharmacovigilance, where the system lacked the capacity to adequately demonstrate harm from these drugs decades ago.[30] This situation indicates a significant historical public health burden from potentially ineffective or harmful drug combinations. The repeated necessity for expert committees and judicial intervention to remove these drugs from the market underscores the challenges in retroactively correcting regulatory oversights and the difficulty in dislodging deeply entrenched products, even when scientific evidence points to their irrationality or risk.

The prohibition of individual drugs such as Rofecoxib (due to cardiovascular risk), Nimesulide (due to hepatotoxicity), Sibutramine (due to cardiovascular risk), and Dextropropoxyphene (due to cardiac electrophysiology impact and overdose risk) illustrates a dynamic and evolving understanding of drug safety.[25] These regulatory actions are often driven by the accumulation of post-market data, advancements in pharmacovigilance, and new scientific findings. What might have once been considered safe or therapeutically beneficial can later be identified as having unacceptable risks, particularly with long-term use or in specific patient populations, as seen with Nimesulide's pediatric ban.[25] This necessitates a continuous reassessment of drug profiles and the maintenance of a robust system for collecting and analyzing adverse drug reactions. The fact that some of these drugs were voluntarily withdrawn globally, such as Rofecoxib by Merck and Sibutramine following FDA recommendations, indicates a strong interconnectedness in global pharmacovigilance and regulatory responses.[39] While India's actions often align with international safety signals, there can sometimes be a delay, as exemplified by Nimesulide being banned in India in 2011, years after its prohibition in other countries in 2000.[25]

4. The Process of Drug Prohibition and Manufacturer Blacklisting

The process by which drugs are prohibited and manufacturers are blacklisted in India is a multi-step procedure involving expert evaluation, formal notification, and various enforcement mechanisms.

4.1. Role of Expert Committees and Advisory Boards (e.g., Drugs Technical Advisory Board - DTAB)

Expert committees and advisory boards play a foundational role in the decision-making process for drug prohibitions. The Drugs Technical Advisory Board (DTAB) stands as the apex statutory body, tasked with advising both the Central and State Governments on technical matters pertinent to the Drugs and Cosmetics Act.[10] Its recommendations are crucial for informing decisions regarding drug prohibitions and other significant regulatory actions.

The recommendations put forth by DTAB for banning drugs are rooted in rigorous, evidence-based evaluations conducted by expert committees. These evaluations meticulously consider the therapeutic justification of a drug or Fixed Dose Combination (FDC), its overall safety profile, and any potential risks it may pose to human beings. This comprehensive scientific assessment forms the bedrock upon which regulatory actions, particularly those initiated under Section 26A of the Drugs and Cosmetics Act, are based.[23]

4.2. Notification and Enforcement Mechanisms

Once a decision to prohibit or restrict a drug is made, it is formally communicated through official channels to ensure legal enforceability and public awareness.

Gazette Notifications: Official prohibitions and restrictions are formally announced through Gazette Notifications. These publications serve as the legal instrument for making such decisions binding. The notifications meticulously specify the drugs or FDCs being banned, the precise legal basis for the action (e.g., Section 26A), and the effective date from which the prohibition takes effect.[3]

Public Notices and Alerts: In parallel with formal gazette notifications, the CDSCO actively utilizes its website to issue public notices and alerts. These communications are designed to inform a broader audience, including healthcare professionals, industry stakeholders, and the general public, about drug bans, instances of "Not of Standard Quality" (NSQ) drugs, spurious or adulterated products, and other critical safety concerns. These alerts are often

categorized (e.g., NSQ Alerts, Medical Device Alerts, WHO Alerts) and provide specific details, including the names of manufacturers and the reasons for non-compliance, thereby serving as a vital public health communication tool.[3]
Enforcement Actions: Beyond outright prohibitions, the regulatory framework provides for a range of enforcement actions against non-compliant entities. These actions, implemented by State Licensing Authorities in coordination with and under the guidelines of CDSCO, include the issuance of show cause notices, orders to stop production, and the suspension or outright cancellation of manufacturing licenses. These measures aim to compel compliance and penalize violations.[8]

4.3. Blacklisting and Debarment of Manufacturers for Substandard Quality (NSQ)

The regulatory response to "Not of Standard Quality" (NSQ) drugs involves a tiered approach based on the severity of the detected defects. Drugs declared NSQ are categorized to guide appropriate legal and administrative actions:

Category A (Spurious and Adulterated Drugs): This category encompasses counterfeit drugs or those found to contain harmful adulterants. Such cases are treated with the utmost urgency, involving immediate investigation, seeking police assistance, and expedited prosecution under Section 36AC of the Drugs and Cosmetics Act. Penalties for these offenses are stringent, including potential life imprisonment and substantial fines, reflecting the severe public health threat posed by such products.[8]
Category B (Grossly Substandard Drugs): This refers to drugs from licensed manufacturers that exhibit serious quality defects due to negligence or non-compliance with Good Manufacturing Practices (GMPs). Examples include products with significantly low active ingredient content, failures in disintegration or dissolution tests, and contamination. Depending on whether criminal intent or gross negligence can be established, these cases may lead to prosecution or administrative measures such as license suspension or cancellation.[8]
Category C (Minor Defects): This category includes drugs with minor quality variations, which may arise from factors like inadequate formulation studies or improper storage. Examples include broken tablets, discoloration, and labeling errors. For these defects, administrative measures, such as license suspension or cancellation, or compounding of offenses, are typically applied. Prosecution is usually considered only when other administrative measures are deemed insufficient.[8]

Examples of manufacturers facing blacklisting or debarment due to NSQ drugs include Jackson Laboratories and Zee Laboratories. These firms have a documented history of their drug samples failing quality tests, leading to their debarment by various state medical procurement bodies between 2018 and 2023.[5] For instance, Jackson Laboratories was blacklisted by the Bureau of Pharma PSUs of India (BPPI) and debarred by states like Odisha and Karnataka for supplying substandard products. Similarly, Zee Laboratories faced debarment by the Tamil Nadu Medical Service Corporation and Assam's National Health Mission office for failed drug tests, and was among 16 pharma companies blacklisted by Nepal in 2022.[5]

Despite the established framework, the enforcement of drug bans and quality standards frequently encounters legal challenges from pharmaceutical companies. These challenges, particularly against Fixed Dose Combination (FDC) bans, often lead to protracted legal battles.[23] Courts have, in numerous instances, granted interim relief to manufacturers, allowing existing stock of banned drugs to be sold in the distribution network. This judicial intervention, while providing immediate relief to companies, can inadvertently prolong the market presence of potentially unsafe or irrational drugs, thereby extending public exposure to these products. This dynamic highlight a persistent tension between regulatory authority, industry interests, and judicial oversight. It underscores the critical need for regulators to present robust scientific evidence and maintain transparent processes to withstand legal scrutiny and ensure that public health priorities are upheld effectively.

Furthermore, systemic gaps continue to affect the efficiency and accountability of drug enforcement. The decentralized nature of drug regulation, with responsibilities shared between central and state authorities, can lead to fragmented enforcement and inconsistencies across different regions. This fragmentation can result in "regulatory arbitrage," where manufacturers might seek licenses or operate in states with less stringent oversight.[19] Compounding this issue are inadequate resources and significant understaffing of drug inspectors at both central and state levels. A 2013 parliamentary committee report, reiterating findings from 2003, recommended a much higher ratio of drug inspectors to manufacturing and sales units, a target that remains unmet.[48] The Central Drugs Standard Control Organization (CDSCO) itself had a sanctioned strength of 504 drug inspectors but a working strength of only 201 as of December 2023.[48] This resource deficit impacts the frequency and thoroughness of inspections, potentially allowing non-compliant practices to persist. Moreover, the absence of a mandatory drug recall mechanism in India further compromises public safety, as substandard or harmful drug batches may remain in circulation even after being

identified.[48] This situation indicates a pressing need for comprehensive regulatory reform to ensure uniform, effective, and timely enforcement across the country.

5. Conclusion

India's regulatory framework for pharmaceuticals, spearheaded by the Central Drugs Standard Control Organisation (CDSCO), is a critical pillar in safeguarding public health. The analysis demonstrates a robust, albeit evolving, system designed to ensure the safety, efficacy, and quality of medicines. A significant and ongoing focus of this regulatory effort is the prohibition of Fixed Dose Combinations (FDCs) and individual drugs deemed irrational or unsafe, often following rigorous evaluation by expert bodies like the Drugs Technical Advisory Board (DTAB).

However, the journey towards optimal drug regulation is marked by persistent challenges. The frequent banning of drugs that have been on the market for decades, particularly FDCs, points to historical regulatory oversights and a reactive rather than consistently proactive approach to post-market surveillance. This situation underscores the critical importance of continuous pharmacovigilance and a dynamic understanding of drug safety, where new scientific evidence can necessitate the removal of previously approved products.

Furthermore, the implementation of drug control measures faces complexities arising from the fragmented regulatory authority between central and state levels, leading to potential inconsistencies in enforcement. This is compounded by resource limitations, including understaffing of drug inspectors, and the absence of a mandatory drug recall mechanism, which can hinder the swift removal of substandard products from circulation. The recurring legal challenges from the pharmaceutical industry against drug bans also highlight the need for regulators to consistently present irrefutable evidence and maintain transparent processes to uphold public health decisions against commercial interests.

In conclusion, while India has made significant strides in strengthening its drug regulatory framework, continuous efforts are essential. A streamlined, well-resourced, and uniformly enforced system, coupled with proactive pharmacovigilance and a clear, mandatory drug recall policy, will be paramount. Such measures would not only enhance patient safety within India but also further solidify the nation's reputation as a reliable and responsible global pharmaceutical producer.