Quality and Efficacy of Medicines in India

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Abstract

The Indian pharmaceutical industry is a global leader, renowned for its extensive range of affordable medicines and high-quality innovation and research. However, recent issues have brought to light troubling concerns about Indian pharmaceuticals, with several red-flagged medications that warrant thorough investigation. The main objective of this study was to assess the quality and effectiveness of Indian pharmaceuticals by examining various drug classifications, safety advisories, the circulation of prohibited drugs, and the challenges related to over-the-counter (OTC) medications. By exploring these multifaceted aspects, the research aimed to identify key factors impacting the reliability and effectiveness of Indian pharmaceuticals, ultimately contributing to improved healthcare outcomes. The literature search was conducted using PubMed Central, ResearchGate, Google Scholar, and Google Search, screening for relevant articles, including annual reports from government agencies and peer-reviewed studies. Additional information was gathered from credible news sources, government websites, WHO product alerts, and data on substandard medicines from India's Digital Sansad. The present study suggests that there is an urgent need for a greater understanding of the problem and revision of laws, improved systematic data collection, regular awareness programmes, and accurate documentation of substandard drug production and distribution.

Keywords: Indian medicines, quality drugs, efficacy of Indian drugs

Introduction

India is hailed as the 'pharmacy of the world', where the booming pharmaceutical sector has a long and distinguished history in innovating and distributing life-saving medicines at the most affordable cost worldwide. In fact, the pharmaceutical industry in India is currently valued at $50 Billion and is expected to reach $130 Billion by 2030[1]. The country is attracting global pharmaceutical companies that are setting up R&D facilities, reflecting its growing prominence in cutting-edge drug development. Despite its focus on affordability, the pharmaceutical sector is committed to maintaining high-quality standards, with ongoing investments and revisions in quality control along with regulatory compliance to uphold its reputation globally. But, even with its distinguished track record of healthcare advancements, the pharmaceutical industry is currently grappling with a wide set of challenges: heightened scrutiny over drug safety and efficacy, regulatory hurdles, complexity in navigating global markets, compliance issues, and extended development timelines.

Recent issues have brought to light troubling concerns about Indian pharmaceuticals, with several red-flagged medications that warrant thorough investigation. Notable cases include child fatalities in The Gambia and Uzbekistan due to Indian cough syrups[2][3] a ban on the import of medicines from 16 Indian companies by the Government of Nepal[4], associations of Indian-manufactured eyedrops with deaths and severe infections including vision loss in the U.S.[5], and recent alerts by the Central Drugs Standard Control Organisation (CDSCO) of

India in which common prescriptions like paracetamol, pantoprazole, iron and folic acid syrup, along with several antibiotics were found as Not of Standard Quality(NSQ)[6][7]. These cases raise serious questions over the safety and efficacy of drugs manufactured in India, where major segments are generic drugs, OTC (Over-the-Counter) medicines, bulk drugs, vaccines, contract research & manufacturing, biosimilars and biologics, whose quality cannot be assessed readily by lay persons or even experts without the aid of quality testing laboratories. The primary aim of this study was to evaluate the quality and effectiveness of Indian pharmaceuticals, the enforcement of quality standards, and the impact of regulatory frameworks on market practices, providing insights into their effects on public health and safety.

Methods and Results

The literature search was performed on two databases: PubMed Central (hosted by the National Institutes of Health) and ResearchGate, and two search engines: Google Scholar and Google Search. The articles were screened for relevance and the ones fulfilling the following criteria were chosen: Annual Reports of Government Agencies and International Intergovernmental Organisations, studies and research papers in the English language published in peer-reviewed journals, and studies that mentioned the regulatory scenario of Indian medicines. The inclusion criteria focused on works published from 2005 onwards. The information from electronic media (credible newspapers, government websites, press releases and public notifications) and product alerts from the World Health Organisation and drug regulatory authorities of other countries have also been included. Data on substandard and NSQ medicines has also been extracted from India’s Digital

Sansad (Lok Sabha questions and responses). The search was conducted from May 2024 to August 2024.

In the study, government research on drug quality has been included to provide a comprehensive overview of current standards and regulations. In a 2009 investigation by India's Central Drugs Standard Control Organisation (CDSCO), the incidence of spurious drugs in the retail sector was estimated at approximately 0.046 % (11 samples out of 24,136 samples)[8]. In the Drug Survey conducted by the Ministry of Health and Family Welfare in April 2015, the proportion of NSQ (Not of Standard Quality) drugs in India was 3.16%, and spurious drugs were 0.0245%[9]. Furthermore, in 2021-2022, 88,844 drug samples were tested, out of which 2,545 were found to be NSQ and 379 were declared as spurious/adulterated drugs[10].

It was found that the Indian pharmaceutical supply chain is susceptible to significant risks, as evidenced by the frequency of medical product alerts issued by WHO and various drug regulatory authorities. This has drawn severe scrutiny to the nation, due to incidents of contaminated Indian medicines leading to fatalities. It was also found that Over-The-Counter (OTC) medicines presently lack a precise legal definition in the country, resulting in ambiguities within their regulatory framework. Moreover, various banned pharmaceuticals remain on the market due to inadequate enforcement of regulatory measures and limited awareness among healthcare professionals.

Discussion

Drugs

According to the World Health Organisation (WHO), a pharmaceutical product (medication/drug) is used to prevent, diagnose, treat, or relieve symptoms of a disease or abnormal condition. Contemporary medicine development usually consists of two phases: the discovery and refinement of the medicine in the laboratory, followed by clinical trials testing the drug's safety and effectiveness in humans. Drugs contain two groups of materials, active ingredients and excipients. The components with a therapeutic effect are known as the active ingredients, whereas the excipients are not therapeutically effective but are required to guarantee that the final dosage form functions as intended. Typical excipients include lactose, preservatives, cellulose, colouring etc. For a healthcare system to function optimally, medicines must meet rigorous standards of quality, safety, and efficacy. These drugs may be categorized into various types, including branded, generic, substandard, counterfeit, or falsified.

Branded and Generic Drugs

When a pharmaceutical company discovers a new medicine, it receives a patent on its new drug. These branded drugs are often expensive since they are newly developed, innovative, and frequently prescribed for hard-to-treat illnesses. The patent usually lasts for 20 years, to give the originating company a chance to recoup its research investment, although this may vary from country to country. Once the patent on a drug expires, a generic version of the medication may be introduced to the market. These generic medicines may differ in minor ways from the branded version but must have similar efficacy.

A generic name refers to the active ingredient of the medicine; drugs which have the same chemical composition as branded drugs are sold under their chemical

name. A generic drug is formulated to replicate the characteristics of an established brand-name drug, including its dosage form, safety, effectiveness, method of administration, quality, performance, and intended use[11]. Therefore, generic medications are off-patent medications produced by businesses other than the original manufacturer. They may be marketed either under an international nonproprietary name, which is a generic designation without branding, or under a trade name, which refers to a branded generic. For example, acetaminophen, often referred to as paracetamol, is a common over-the-counter drug. Calpol, Crocin, Dolo, etc. are the brand names or the trade names of the Paracetamol given by different manufacturers in India[12].

Generic drugs can aid the provision of healthcare to a wide patient population, particularly in developing countries as they are comparatively cheaper. However, generic drugs should be marketed only if they match the quality standards of the original drug. To ensure this, factors such as purity, potency, and stability must be meticulously controlled within defined parameters. Today, the nation excels as the world's largest producer of generic drugs, offering an extensive array of approximately 60,000 brands across 60 therapeutic categories. It commands a substantial 20% share of the global market by volume and stands out as a premier global manufacturer of vaccines[1].

Generic drugs, with their significantly lower costs, make essential medications more accessible and affordable. On August 2, 2023, the National Medical Commission's Registered Medical Practitioner (Professional Conduct) Regulations, 2023 were published[13]. A significant aspect of these regulations was the mandate that medications must be prescribed solely by their generic names, rather

than their brand names. Pharmaceutical businesses and medical associations including the Indian Medical Association and the Association of Physicians of India strongly objected to the regulations, citing lack of consultation and conjecture over the quality of generic drugs in India.

The following is an extract from an email by the Indian Medical Association (signed by Dr Sharad Kumar Agarwal, National President, IMA and Dr Anilkumar J Nayak, Honorary Secretary General, IMA) to the Prime Minister of India, Union Home Minister of the Government of India and the Chairman of National Medical Commission, dated 14.08.2023, which highlighted their concerns regarding the regulations[14]:

"....The regulation is mandatory for doctors to prescribe only generic drugs. It is a matter of great concern for IMA since this directly impacts patients' care and safety. Generic promotion needs to be genuine. Running trains without tracks is how the present promotion of Generic drugs by NMC appears to be. NMC insists on its ethics guidelines to write prescriptions only in generic names. This measure is just shifting the choice from a medical practitioner who is primarily concerned, trained and responsible for the patient's health than a chemist/person sitting in a chemist shop, who is selling drugs. This naturally wouldn't be in the best interest of the patient....If doctors are not allowed to prescribe branded drugs, then why such drugs should be licensed at all, given that modern medicine drugs can be dispensed only on prescription of doctors of this system……The biggest impediment to Generic drugs is the uncertainty about it's quality. The quality control in the nation being very weak, there's practically no guarantee of the quality of drugs and prescribing drugs without assured quality would be detrimental to patient health. Less than 0.1% of the drugs manufactured in India are tested for quality.

This step should be deferred till the Government can ensure the quality of all the drugs released into the market. Patient care and safety are not negotiable…." (extracted from the email, found in the IMA NEWS Vol.62(8)(pp. 7–38) which was publicly accessible[14])

In the email, the IMA also suggested a solution to the problem :

"....Rather than taking the NMC route the Government should take the Pharma route and ban all the branded drugs. Government allows several categories like Branded, Branded Generic and Generic and permits the Pharmaceutical Companies to sell the same product at different prices. Such loopholes in law should be plugged. IMA demands a foolproof system of quality assurance before switching over to Generic drugs. IMA had been demanding for long that only good quality drugs should be made available in the country and prices should be uniform and affordable. IMA urges the Government to have 'one drug, one quality, one price' system whereby all brands should be either sold at the same price which should be controlled or banned and only generics allowed while ensuring highest quality of these drugs……If the Government and NMC want all the Doctors in the country to prescribe only generic drugs, they should simply order all pharmaceutical companies to manufacture all the drugs without brand names…" (extracted from the email, found in the IMA NEWS Vol.62(8)(pp. 7–38) which was publicly accessible[14])

In light of significant criticism and post-facto consultations, the Regulations were kept in abeyance on August 23, [15].

Substandard, Counterfeit and Falsified Drugs

Substandard medicines are those that do not conform to the established quality standards and specifications [16]. To be deemed compliant, a drug must satisfy rigorous quality criteria not only at the time of its release but also consistently throughout its shelf life, in accordance with the regulations applicable in the region where it is distributed. Any formulation of a medication may be regarded as substandard if it has either too much or too little of the Active Pharmaceutical Ingredient (API) compared with the formulation specifications. Consequently, while these drugs are intended to be genuine pharmaceutical products, they are often produced with cost-saving measures that compromise quality, such as bypassing Good Manufacturing Practices (GMP) or using inferior raw materials.

The World Health Organization (WHO) defines counterfeit drugs as those drugs that are deliberately and fraudulently mislabelled concerning their identity or source. These drugs often replicate the appearance, design, and packaging of legitimate products, thus misleading consumers while failing to meet the required quality and efficacy standards. Examples of counterfeiting include a cheap antibiotic re-packaged and re-labelled as a more expensive one.

Falsified medicines are fraudulent products that claim to be legitimate and authorised drugs but are fake medicines and not genuine [17]. These are highly likely to be of substandard quality, possibly containing no API or ingredients of low quality, deliberately and fraudulently mislabelled concerning their identity or source, and have fake packaging or ingredients in wrong doses.

In light of concerns about medication safety, the government has undertaken studies to systematically assess and quantify the prevalence of substandard medicines throughout the country, aiming to identify areas of risk and ensure the effectiveness and safety of pharmaceutical products. In a 2009 investigation by India's CDSCO, samples were analyzed from 61 widely used oral solid dosage (OSD) formulations across nine therapeutic categories: anti-infectives, anti-malarials, anti-tuberculosis drugs, steroids, antihistamines, cardiovascular medications, anti-diabetics, NSAIDs, and multivitamins[8]. The study took place between November and December 2008, with a total of 24,780 samples gathered from approximately 40,000 pharmacy outlets. Among these, 644 samples were identified as SALA (Sound Alike and Look Alike) products, which resembled branded drugs in name or packaging but were not identical. Out of the remaining 24,136 samples, only 11 were deemed non-genuine upon physical examination by manufacturers. Consequently, the incidence of spurious drugs in the retail sector was estimated at approximately 0.046 % (11 samples out of 24,136 samples).

Another study was conducted by the Ministry of Health and Family Welfare, wherein a countrywide Drug Survey was rolled out in April 2015[9]. This survey encompassed 47,954 samples drawn from retail outlets, government sources and ports. Out of these, 633 samples (1.32%) were not among the 224 designated molecules for the study. Further, 309 Drug samples (0.64%) were found either damaged or lost in transit. The remaining 47,012 samples were subjected to rigorous testing and analysis. The analysis indicated that 13 samples were identified as spurious, whereas 1,850 samples were classified as 'Not of Standard Quality' (NSQ). Consequently, the proportion of NSQ drugs in India was determined to be 3.16%, while the prevalence of spurious drugs was 0.0245%.

Dr. Bharati Pravin Pawar, Former Minister of State for Health and Family Welfare of India, in response to the Lok Sabha question on spurious drugs, revealed the year-wise data of NSQ/Adulterated/Spurious Drugs reported, seizures made and enforcement action taken thereof (as of 3rd February 2023), which are as follows[10]:

Table 1 :

Year-wise data of NSQ/Spurious Drugs reported, seizures made and enforcement action taken thereof

Year (1st April of preceding year to 31st March of the following year)	No. of drug samples tested	No. of drug samples declared Not of Standard Quality (NSQ)	No. of drug samples declared spurious/ adulterated	No. of prosecution launched for manufacturing, sale & distribution of spurious /adulterated drugs	No. of persons arrested	No. of raids conducted
2014-15	74199	3702	83	152	85	14042
2015-16	74586	3703	234	289	59	3648
2016-17	76721	2780	123	186	106	10921
2017-18	82599	2783	236	131	163	7067
2018-19	79604	2549	205	484	153	33492
2019-20	81329	2497	199	421	220	15641

2020-21	84874	2652	263	236	164	20922
2021-22	88844	2545	379	592	450	15973

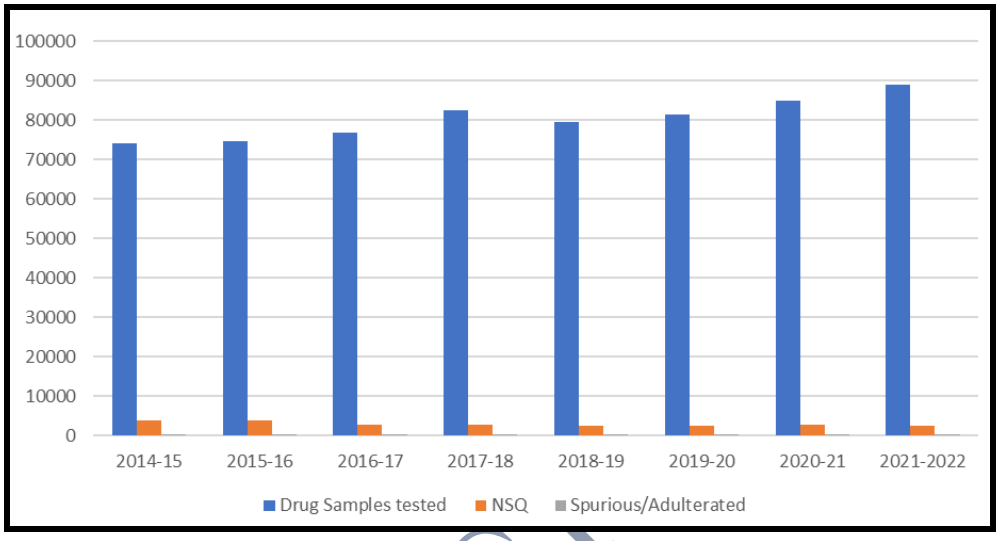

Figure 1: Year-wise data of the number of Drug Samples tested, NSQ and Spurious Drugs reported

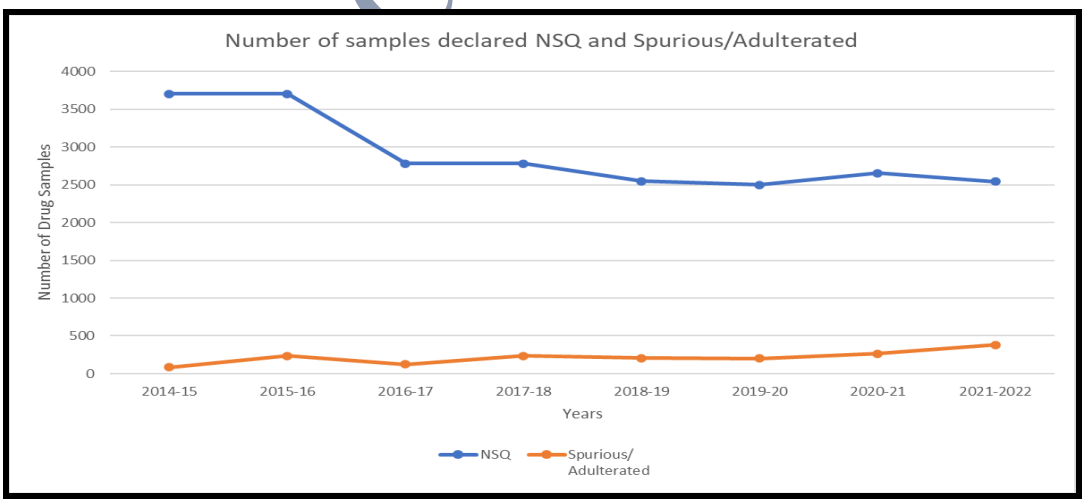

Figure 2: Year-wise trend of NSQ and Spurious/Adulterated Drugs reported

The data reveals a steady increase in drug samples tested, reflecting proactive quality measures. While NSQ samples have decreased, spurious/adulterated samples have risen, indicating concerns over counterfeit drugs, possibly driven by affordability or enhanced detection capabilities uncovering previously undetected issues. Despite quality improvements, the trend highlights the need for vigilant regulation, updated detection methods, and adaptive strategies to address emerging threats.

In fact, in a recent alert dated June 2024, the CDSCO of India identified 52 pharmaceuticals as NSQ, including common prescriptions like paracetamol, pantoprazole, iron and folic acid syrup, along with several antibiotics [6][7]. This suggests that even common and essential medications are not consistently meeting quality standards, which could have serious implications for the public.

In contrast to the government investigations, many scientific literatures as well as media reports often quote figures ranging from 10-35% prevalence of poor-quality drugs. A 2009 pilot study evaluated the concentration of active ingredients in antimalarial, antibiotic, and antimycobacterial drugs [18]. Random samples were collected from pharmacies in urban and peri-urban areas (peripheral-urban) of Delhi and Chennai and compared against internationally accepted standards. 12% of all samples tested from Delhi and 5% of all samples texted from Chennai failed either one or both tests and were substandard. However, it was observed that the sample size may not be large enough to make concrete conclusions[19].

Counterfeit drug data is often under-represented by governments to protect healthcare confidence, while media and rival pharmaceutical companies often amplify concerns without verification, damaging India's reputation and global

market position. The lack of standardized definitions, varying quality standards, and inconsistent legal frameworks further complicate accurate reporting, making it challenging to assess and address counterfeit drugs globally.

Medical Product Alerts

Medical Product Alerts are issued to notify the public about hazardous medical products and to prompt

heightened awareness and regulatory responses. The World Health Organisation has issued various medical product alerts on medicines manufactured in India and imported to India. In 2023, the alerts on medicines by Indian manufacturers included a batch of substandard (contaminated) syrup medicines (Paracetamol and Chlorpheniramine Maleate) that was identified in the Republic of Iraq[20], substandard syrup medicines identified in the Marshall Islands and Micronesia (Federated States of)[21], batches of Tetracycline Hydrochloride Ophthalmic Ointment USP 1% with quality issues[22], and contaminated liquid dosage medicines identified in Uzbekistan and Cambodia [23].

Alerts on imports in India include Falsified 'Defitelio' (defibrotide) identified in India and Türkiye in 2023 [24], falsified Intratect (Human normal immunoglobulin) identified in India, Brazil, Bolivia(Plurinational State of) and Egypt in 2021-22[25], falsified DESREM (Remdesivir) recognized in India and Guatemala in 2022[26], and falsified Soliris identified in India Argentina, Estonia and Uruguay in 2021[27]. Even in developed nations with stringent regulations, the frequency of alerts suggests that the global pharmaceutical supply chain is susceptible to risks. While the U.S. and Europe experience WHO alerts related to counterfeit products, India has faced severe scrutiny due to incidents of contaminated medicines leading to fatalities.

The US FDA is often regarded as the largest and most influential regulatory authority in the world concerning the approval and oversight of pharmaceuticals and medical devices. FDA's stringent standards for drug approval often serve as a model for other regulatory authorities around the world as well.

Recently the FDA's heightened scrutiny has been driven by several significant scandals, including incidents where contaminated cough syrups were linked to fatalities in Gambia and Uzbekistan[2][3], as well as concerns over eye drops manufactured in India and imported into the U.S. under the brand names EzriCare Artificial Tears and Delsam Pharma's Artificial Tears, which were associated with three deaths, severe infections, vision loss in eight patients, and the surgical removal of eyes for four patients[5].

In fact, further investigation into the associations between cough syrups made in India and child fatalities in Uzbekistan and the Gambia brings to light the deaths of 12 Jammu children, who passed away in December 2019 and January 2020 as a result of ingesting tainted medication produced by a Himachal Pradesh-based company ‘Digital Vision’[28]. The medicine was found to contain high amounts of diethylene glycol, which led to kidney poisoning[28]. Tragically, contaminated cough syrup has been linked to diethylene glycol poisoning in India before, as evidenced by the deaths of 36 children in Gurgaon in 1998[29], 11 patients in Bihar in 1988[30], 14 patients in Mumbai in 1986[31] and 15 children in Madras in 1972[30]. Additionally, the Nigerian drug control agency issued a public alert in June 2023 regarding cough syrups and oral paracetamols imported from the Republic of Liberia and manufactured in India. These products were flagged as substandard, containing harmful toxins not typical for such formulations as they

failed to meet safety standards for acute oral toxicity, which resulted in the death of five laboratory animals during testing[32].

Overall, India's pharmaceutical sector is under significant scrutiny from both domestic and international regulatory bodies. The persistent alerts highlight the pressure on Indian manufacturers to adhere to high standards of quality and compliance. However, this scrutiny is likely to drive ongoing efforts to enhance regulatory practices and manufacturing processes.

Banned Drugs marketed in India

In developing countries such as India, banned pharmaceuticals remain on the market due to inadequate enforcement of regulatory measures and limited awareness among healthcare professionals. Despite being banned by the US FDA for causing serious side effects like severe kidney and liver damage, drugs such as Nimesulide, Rofecoxib, and Phenylpropanolamine, along with other Over-The-Counter (OTC) medicines, continue to be available in India[33]. Nimesulide was banned for children under 12 years of age on February 12, 2011 [34] due to hepatotoxicity but is still being prescribed by some older practitioners to adults as it is effective in counteracting inflammatory pain and also because of the lack of awareness regarding an update on the drug [35]. Phenylpropanolamine (commercial examples: Vicks Action 500) was also banned in 2011 [33] but is still prevalent due to commercial advertisements [35]. It has been associated with the risk of hemorrhagic stroke, still, it is a commonly used banned drug for colds and coughs[33]. Analgin (metamizole) is manufactured and marketed due to its excellent pain-relieving properties, but consumers are usually unaware of its adverse effects [35]. Analgin and its formulations for human use were initially

suspended in the country in June 2013[36] but later the government revoked the notification in 2014[37], subject to the condition that manufacturers must mention on their packaging and promotional literature that the drug is indicated for severe pain, pain due to the tumour, and for bringing down temperature in refractory cases when other antipyretics fail to do so. Other examples include Nefopam (the most preferred analgesic for post-operative pain but has been associated with a higher incidence of occurrence of epilepsy)[35], Nitrofurazone (available as an antibiotic cream but evidence suggests carcinogenic properties)[35], Prophiphenazone (prescribed for inflammatory pain but has the adverse effect of bone marrow depression) [35] etc.

Some drug combinations, like paracetamol, with NSAIDs or other analgesics, can worsen adverse effects and are considered irrational and banned[35]. In India, however, these formulations were still available. It was only recently that the government prohibited 14 FDCs, as per the gazette notification dated 02.06.2023 [38]. This included a ban on Nimesulide + Paracetamol dispersible tablets.

Regulatory oversight in India is inadequate, with weak enforcement of global safety standards, allowing unsafe drugs to remain in circulation. The lack of coordination between the DCGI and State Drug Controllers delays drug recalls and bans. Misleading marketing strategies from pharmaceutical companies contribute to continued use of banned drugs. Additionally, high costs and limited access to newer medications force many patients to rely on older, ineffective drugs. This combination of factors exacerbates the use of unsafe drugs in India.

Problem of Over-the-Counter Medicines

In India, for minor health issues like coughs, fever, and allergies, patients often consult pharmacists who provide Over-The-Counter (OTC) medications without a prescription. In India, OTC medicines lack a clear legal definition. Essentially, a drug is classified as OTC unless it's explicitly designated as prescription-only. The Drugs and Cosmetics Act 1940 classifies medications into different schedules. For example, drugs listed under Schedules H, H1, and X must carry labels indicating that they can only be sold with a prescription from a licensed medical practitioner[39]. The medicines which do not fall under this category can be given without prescription through pharmacists and drugstores in India. In a country like India, where the doctor-to-patient ratio is pitifully low, designating OTC drugs as a distinct class can increase access to safe medications and bring clarity to the regulation framework regulating those medications [40].

Self-medication is widespread in India, with prescription drugs often sold without a prescription like OTC medicines. The lack of official data on self-medication highlights a knowledge gap, though independent studies have attempted to address it, yielding inconsistent results. For example, a community-based cross-sectional study published in 2024, conducted in the urban and rural catchment areas of Uttar Pradesh, India, found a self-medication prevalence of 66.4% among 440 adults[41]. Another community-based study conducted from June to December 2019 in an urban area of Central India found a 60% self-medication prevalence among 400 individuals at a tertiary health care centre (UHTC)[42]. Furthermore, a descriptive cross-sectional study carried out from July 2017 to August 2017 in 412 families residing in urban slums near the Government Medical College, Jabalpur, revealed that 42.7% (176 out of 412) of the participants practised self-medication[43]. Additionally, a community-based cross-sectional study conducted

in 2017 in a rural field practice area of Vydehi Institute of Medical Sciences and Research Centre, Bengaluru, found that 40.5% of the 269 surveyed individuals practised self-medication [44]. In Chennai, Tamil Nadu, a study conducted between 2016 and 2017 involving 610 patients visiting a dental hospital found that over 70% of the dental patients engaged in self-medication[45]. The rate of self-medication varies significantly across different sub-populations, reflecting a broader diversity in reported practices and reasons for self-medication. This variability underscores the need for more research to identify the underlying factors driving self-medication in India.

The most prominent reason for self-medication is convenience, as over-the-counter drugs are readily available and serve as a quicker solution to minor ailments. Other factors include perceived mildness of one's illness, past encounters with similar symptoms, feelings of discomfort or embarrassment associated with discussing symptoms, and fear of invasive procedures or diagnostics. Aggressive marketing and advertising by pharmaceutical companies can also influence individuals to use certain medications without consulting a healthcare provider.

Individuals with a strong understanding of medications and their use are more likely to self-medicate, trusting their knowledge. In a 2024 study published in the Journal of Family Medicine and Primary Care, self-medication prevalence among medical students in urban India was alarmingly high at 83.9% [46]. The primary sources for self-medication included older prescriptions and pharmacist stores, with common colds being the most cited reason. Notably, 73.3% of students used non-OTC drugs, highlighting significant breaches in the regulation of prescription-only drug sales[46]. Additionally, 6.1% experienced adverse drug reactions, and 0.6% continued self-medicating despite these reactions[46]. Moreover, 18.9% of

medical students would recommend self-medication to others, highlighting the urgent need for enhanced education, stricter regulations, and improved monitoring to address and prevent this risky [46]. The easy access to non-OTC medicines reported by students further stresses the need for more stringent controls on drug accessibility, dispensation and storage.

Limitations

The limitations of the study include the following: first, the reliance on secondary data sources may limit the generalizability of the findings, as the insights might not fully represent the diverse complexities of the Indian pharmaceutical landscape. Second, the lack of standardized definitions and varying quality standards across countries complicate accurate reporting of counterfeit drugs, resulting in inconsistencies in global assessments. Additionally, self-medication rates differ greatly among sub-populations, indicating a need for better research on its driving factors and correlation with the use of over-the-counter medicines in India. There is also substantial scope for further research that could address these limitations by employing quantitative methodologies to complement qualitative findings, thus providing a more holistic view of pharmaceutical quality and effectiveness.

Conclusion

While the Indian pharmaceutical industry is poised for significant growth and innovation, it must address and resolve the arising multifaceted challenges. To ensure that drugs are considered acceptable, they must satisfy stringent purity criteria and be produced in facilities that adhere to internationally recognized standards. The emphasis on quality assurance in generics is vital as they play a crucial role in making healthcare more accessible as they are more cost-effective

than branded alternatives. There is an urgent need for revision of laws, improved systematic data collection, regular awareness programmes, and accurate documentation of substandard drug production and distribution. Despite international bans, many drugs are still marketed and used due to insufficient oversight and aggressive advertising. The lack of coordination between regulatory bodies and the high cost of newer medications further perpetuates the use of outdated drugs. Moreover, the vague classification of OTC drugs has led to a high prevalence of self-medication, often due to convenience and limited medical access. This trend poses significant risks, including improper use of prescription drugs and an increase in the rate of adverse drug reactions. It also highlights the need to establish high standards of professional conduct for pharmacies to ensure efficient pharmaceutical services in the public interest.

Unless Indian regulatory standards and quality checks are aligned with the world's top benchmarks, Indian drugs will always face scepticism, like a cracked foundation beneath a towering structure.

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