THEME EDITORIAL

# Compromised quality of medicines: a regulatory failure

**SANDHYA SRINIVASAN, VEENA JOHARI**

January 1, 2026, was a milestone of sorts in the Indian drug industry. As of that date, all manufacturers, small and large, are required to comply with the December 2023 amendments to Schedule M of the Drugs and Cosmetics Act, 1940, and Rules, 1945, that relate to Good Manufacturing Practices (GMP) and Quality Risk Management [1]. The amendments detail the requirements of premises, plant, and equipment for pharmaceutical production. The change, if implemented, is intended to upgrade Indian pharmaceutical manufacture to the standards of the World Health Organisation's Guidelines on Production, that include GMP [2]. They would also move closer to the International Council Conference for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). ICH brings together regulatory authorities and the pharmaceutical industry to discuss issues relating to registration of drugs, and has developed quality guidelines based on GMP [3].

The Indian drug industry has been under the scanner for some years, and the general impression is that Indian drug manufacturers produce sub-standard drugs. Between April 2024 and March 2025, the Central Drugs Standard Control Organisation (CDSCO) tested 1,16,323 samples, of which about 3 percent were substandard (not meeting quality standards and specifications according to GMP), and about 0.2 percent were spurious and adulterated drugs [4]. The CDSCO's sampling process is not known; but whatever the real prevalence is, drug quality is a vital concern.

The change in the law is expected to improve the quality of medicines manufactured, sold, and exported by Indian pharmaceutical manufacturers. However, there are many challenges to address before we can be assured of quality medicines. The reality is that much is wanting.

## The Indian pharmaceutical industry

The Indian pharmaceutical industry is the third largest by volume in the world. It is the largest supplier of generic drugs (copies of drugs, that may be off-patent)[a] whether unbranded or branded, accounting for 20 percent of the global supply. The industry manufactured about 60,000 generic brands across 60 therapeutic categories in 2024-25 [5].

Still, there is persistent distrust of the quality of some pharmaceutical products, and of whether they meet the required standards. This distrust is heightened by the periodic reports of fraudulent practices, adulteration, manufacturing violations, and corruption. Consequently, well-known branded drugs of the innovator or generic variety are perceived to be of better quality than lesser-known branded generics, though the active ingredient is the same in all generic versions of the medicines, as well as in the innovator product.

However, substandard medicines have been found in small, medium and large generic drug companies as well as in innovator companies [6,7]. Big pharma and the generics industry (big, medium, and small) have had to recall substandard drugs [8-15] and take corrective action.

In countries with a strong regulatory apparatus, substandard drugs are identified faster, with swift corrective action that may range from warning notices to correct weaknesses, to orders to recall substandard drugs, to penalties for violation [6,7,12]. In some instances, the manufacturers may recall substandard drugs of their own volition [8-11]. Manufacturers of substandard drugs may also face litigation, and may need to pay compensation to those harmed by substandard, adulterated, misbranded, or spurious drugs [13].

## Standards for good quality medicines

There are three elements to ensuring the quality of pharmaceutical products: the standards of manufacturing, laws and rules to implement those standards, and their actual implementation.

The first element is the standards established for pharmaceutical products, including active pharmaceutical ingredients and excipients, manufacturing processes, the final product, and its distribution and storage. These standards are laid down in GMP guidelines. Indian GMP is included in the Revised Schedule M of the Drugs and Cosmetics Act, 1940 and Rules, 1945 [1]. The law requires government authorities to issue manufacturing licences, as well as to inspect manufacturing units and test products prior to and during the production and distribution stages. Drug regulators and inspectors play a prominent role at all stages of these processes.

Standards of quality include certain products and processes that may pose a risk to the user. For this reason, Quality Risk Management is built into GMP guidelines of the Revised Schedule M. The risks must be assessed, based on the available scientific evidence, and steps taken to mitigate or manage them, following a specified procedure. The process of determining "acceptable risk" and the scientific basis of this determination require to be made publicly available.

Some requirements under the Revised Schedule M have ethical implications. For example, producers of certain generic drugs must provide clinical trial data from bioavailability and bioequivalence (BA/BE) studies to establish that their version of the drug is the same as the innovator drug. This raises the question of whether healthy people, on whom BA/BE studies are usually conducted, should be subjected to drugs they do not need, with all the risks linked to those drugs.

The quality of drugs may get compromised due to variations at various stages in the production process, the use of incorrect quantities of the active pharmaceutical ingredients and excipients; impurities or contaminants introduced during production, packaging, distribution, supply, or storage, etc. Quality can also be compromised through deliberate adulteration or use of substandard raw materials or processes. GMP lays down the steps to identify such issues during the production process. The law also requires drug inspectors/ regulators to test batches of finished drugs to identify batches of substandard drugs, as well as instances of deliberate adulteration, and to take appropriate action.

Once a drug is manufactured and sold, quality control is supposed to be done, and patients are protected through a pharmacovigilance programme. Complaints of harm following the use of a drug may be reported by healthcare professionals, or by patients themselves, for investigation.

If a drug is found to be substandard, the manufacturers, authorities, and courts (where there are legal cases), must assess the level of harm — as serious, life-threatening, reversible, self-limiting, or minimal/ negligible/ not likely to cause harm. They must also establish which stage it has reached in the drug distribution chain — whether it is still with the wholesalers, or with retailers, or whether it has reached consumers. Based on this assessment the manufacturer must ensure that the potential harm has been minimised or eliminated by recalling all batches of the substandard product. The manufacturer will also be required to identify the reason for poor quality, and modify the processes to reduce this risk to products. If the drug has reached consumers, the regulator and manufacturer will issue warnings. The manufacturer is required to verify that people who purchased or received the substandard drug are notified about the recall, and about the drug's potential harm, and advised to return the drug to the manufacturer [10,11]. The revised Schedule M requires manufacturers to establish a written procedure in the form of Standard Operating Procedures for effective recall of products [1].

Finally, the legal process of manufacturing and distributing substandard, adulterated, misbranded, or spurious drugs, is based on evidence placed before the court, the extent of harm or potential harm, and the corrective action taken by the manufacturer. Fraudulent action, including deliberate use of substandard products, requires strict punitive action.

## Regulation and its implementation

Is India's regulatory structure able to ensure that its huge and varied pharmaceutical industry meets these standards? Doing so will need correct implementation of the laws within which the standards are embedded, with transparency, and zero tolerance of corruption. We do not have a good record in this so far.

There is much secrecy and opacity in how government authorities approve medicines, and there is a nexus between industry, regulators and the medical profession. The Mashelkar Committee exposed this in 2003 [14]. The 59th Parliamentary Standing Committee report on the functioning of CDSCO had similar findings in 2012 [15]. A more recent case of opaque functioning was revealed during the Covid-19 pandemic. The regulator approved Covid-19 vaccines before the clinical trials were completed, without examining all the data, and despite reports of ethical violations that would affect the data. Post–approval data has not been made available in the public domain [16], giving rise to serious doubts about the vaccines' safety and efficacy. Such a lack of transparency in the functioning of the drug authority also leads to distrust and hesitancy among people about taking drugs and vaccines.

Clearly, such opacity, suggestive of violations of the regulatory process, is inevitable in a broken regulatory system. The most urgent change required in regulation is to make the entire approval process of pharmaceutical products open and transparent, and to make all (anonymised) clinical trial data available in the public domain. Quality is ensured when all data on efficacy and safety is thoroughly examined by the regulator, conflicts of interest are declared, processes are documented in detail, and the data is available for the public to scrutinise, keep tabs on what is being approved, and raise questions if there are any red flags or issues about the drug's safety and efficacy.

Further, behind the ensuring of quality pharmaceutical products and good standards, stands a robust system of implementation and monitoring. The drug control authorities at the central and state levels have not fulfilled their responsibilities in this regard.

In all the cases of adulterated drugs harming patients, discrepancies had been found in the approvals, inspections, and/or processes of manufacture. Manufacturers were arrested for their criminal actions, and in some cases, the drug inspectors were also arrested for their criminal negligence [17].

A weak regulatory system allows for poor quality and irrational pharmaceutical products to enter the market with the potential to harm people. While the law criminalises certain activities, the process is long drawn out.

As the Ranjit Roy Chaudhury Expert Committee noted:

> *The effectiveness of drug regulation depends on the priority accorded to this activity, investment made in terms of infrastructure, offices and laboratories with the capacity to do testing of chemicals and biologicals, and an optimum number of qualified and experienced drug regulators, inspectors, etc. available at the Centre and in the states. Drug regulators have to function with clear mandates of transparency and accountability.* [18]

Unless accountability is integrated into the system, improving quality and standards of drugs will be a distant dream.

## Counterposing quality and cost — a false dichotomy

The other major question in the quality debate is: what needs to be done to ensure that the revised standards do not result in increased drug prices and reduced access to essential medicines? The high cost of healthcare, including medicines, already forces many Indians to forgo treatment, or fall into debt to obtain treatment [19]. The concern about increased manufacturing costs leading to higher prices of medicines must be viewed in the context of the very high profit margins of many brands of drugs.

Campaigns for affordable medicines, led by patient groups and civil society are among the forces that have made the treatment of many diseases affordable. Yet, irrational, unnecessary, and unsafe drugs proliferate, and the cost of medicines in India accounts for the bulk of healthcare expenditure, and healthcare expenditure is a significant cause of indebtedness in the country [19].

The decline of the public sector in drug manufacture has contributed to the problem. The government must take back its responsibility to provide rational and affordable drugs to the people. It must revive the public sector drug industry. Furthermore, given that the bulk of drugs supplied in the country are manufactured in industrial units that will not meet the revised standards without substantial resources [20], the government must also provide technical and other support to existing units to upgrade facilities towards meeting GMP requirements.

The articles in this thematic collection on drug regulation in India discuss many of these issues.

The role of the government is central in the article by **Abrol, John** and **Singh** that sets the context for this discussion. They argue that the question of drug quality must be situated in the perspective of India's industrial policy for drug manufacture [20]. India's Patent Act of 1970 and India's Drug Policy were passed to enable the establishment of an industry self-sufficient in the production of essential medicines at affordable prices, with a strong public sector manufacturing essential drugs and vaccines. However, this vision was not realised. India's signing of the Trade Related Intellectual Property Rights agreement forced it to change its drug policy, dismantling a self-sufficient industry and prioritising exports rather than the interests of Indians. The use of loan licensing for the domestic market, maximising of profits, and poor regulation enabled the flourishing of a drug industry where a large proportion of drugs is produced in micro, small and medium enterprises (MSME). This industry has focused on producing expensive, irrational and unsafe medicines. The authors suggest that while enforcing the revised Schedule M may be seen to threaten the medium and small enterprises sector, it is the government's responsibility to ensure that the MSMEs are upgraded to meet the necessary standards.

In fact, the story of drug regulation might have been very different if India's public sector pharmaceutical industry, which was set up with the vision of manufacturing essential medicines, existed in any substantial form today. Instead, public sector units have been shut down over the years, under various pretexts. For example, in 2008, vaccine plants manufacturing the bulk of vaccines for the universal immunisation programme, were shut down on the argument that they did not meet the World Health Organization (WHO) standards. The shift of manufacture to private industry was meant to be temporary, pending the establishment of new upgraded facilities. However, those facilities never materialised [21].

Another commonly expressed view of poor drug quality is that it is the result of corruption — bribes by manufacturers to inspectors, companies to regulators, and so on. While this is certainly the most obvious type of corruption, **Ghodajkar** and **Priya** [22] find that commonly used frameworks on understanding corruption are ahistorical and without a larger context. They present another, systemic understanding of corruption that takes into account the socioeconomic context, and the "medical industrial complex" — the network of providers and industries in healthcare — to describe institutionalised forms of corruption.

Ghodajkar and Priya's framework is relevant to the various legitimised forms of corruption in healthcare. It applies to the nexus between industry-funded research and compromised regulatory bodies that enables approval of unsafe drugs on the basis of flawed data; the acceptance of lobbying as a legitimate activity; the practice of philanthropic foundations using leverage money to influence the government's choice of health interventions; the opacity of pharmaceutical companies using public sector research for super-profits; the patent regime that permits pharmaceutical companies to delay the entry of generic versions once the drug is off patent by applying for multiple patents, and so on. Such legitimised practices enable criminal behaviours such as the recently exposed racket in counterfeit cancer medicines. These could occur, at least partly, because of the drug's legally permissible extortionate price, leaving patients desperate for a discount, and criminals waiting to exploit that desperation [23].

**Nagarajan's** commentary [24] on the most recent spate of child deaths from adulterated cough syrup is a scathing critique of the regulatory apathy towards drug quality and its impact on people's health and lives. The system fights transparency and public scrutiny, and there is almost no information in the public domain on regulators' inspections, their findings and the action taken against violations. Regulators themselves are not held accountable for their negligence. Companies that have repeatedly violated the law continue to function; when they are forced to shut down, they resurface under new names. The corruption extends to the medical profession, as doctors are influenced by financial incentives to prescribe irrational and sometimes dangerous drugs. There are multiple failures of the health system, from the failure to pick up early signs of poisoning, to an ineffective adverse event reporting programme, and an absence of any mechanism for country-wide recall of contaminated or toxic medicines.

**Bhargava** [25] suggests that the question of drug quality cannot be viewed in isolation. His analysis covers the macro level of policy and regulation; the meso level of the pharmaceutical industry and professional bodies; and the micro level of the interactions of individual providers and patients. The crisis of medicines today must be addressed through multiple responses, from evidence-based approval to a strong regulatory system, cost-based pricing, and availability of essential drugs. Bhargava concludes with guidelines on criteria for ethical prescription.

**Chandra** and **Unnikrishnan** [26] review the child deaths following contaminated cough syrup as failures of both regulation and rational medicine, describing the frequent prescription of cough syrups to children under five for self- limiting illnesses as "ethically indefensible". The authors propose a stewardship model for safe paediatric drugs involving four elements — clinical practice, quality assurance, market surveillance, and public communication to counter misconceptions.

The sixth article in the theme issue by **Srinivasan, Nadimpally** and **Bhargava** [27] pays tribute to Chandra Mohan Gulhati, a colossus of the rational drug movement, campaigner for drug price control, and critic of a regulatory system compromised by unethical elements in the pharmaceutical industry and the medical profession.

The articles in this theme issue on regulation of medicines present the current debates in the context of the right to health and to rational, quality and affordable medicines. Expert committees have recognised the problems within the drug regulatory system, and recommended various steps to overhaul it. The revised Schedule M is certainly a move in the right direction. The question now is: how will the government implement these and the other changes, and what will the impact be on the drug industry, and people's health?

***[a]Note:***

*The term "generic drug" refers to copies of the innovator drug. Generics enter the market usually after the patent on the innovator drug expires. Generic drugs may also enter the market either on a voluntary licence by the innovator, or through a compulsory licence issued by the government on patented drugs. Prior to 2005, when the Indian Patents Act, 1970, did not recognise product patents, generic drug manufacturers reverse engineered and manufactured the drugs.*

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**Authors: Sandhya Srinivasan** (corresponding author — sandhya199@gmail.com), Independent Journalist, Bandra West, Mumbai 400 050 INDIA; **Veena Johari** (courtyardattorneys@gmail.com), Advocate, Courtyard Attorneys, Worli, Mumbai 400 030 INDIA.

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