familys-pharmacy-10291931/
22. Singh A. Coldrif row: Madhya Pradesh took two weeks to raise red flag on cough syrup deaths; accused doctor's bail rejected. *Times of India*. 2025 Oct 8 [Cited 2025 Oct 22]. Available from: https://timesofindia.indiatimes.com/india/coldrif-row-madhya-pradesh-took-2-weeks-to-raise-red-flag-on-cough-syrup-deaths-doctors-bail-rejected/articleshow/124399813.cms
23. Kaur B. The curious case of a 'Killer' drug with contradictory toxin test results at different govt labs. *Wire.in*. 2023 Sep 9[Cited 2025 Oct 22]. Available from: https://m.thewire.in/article/government/curious-case-of-a-killer-drug-with-contradictory-toxin-results/amp?utm=relatedarticles
24. Ray K. Cough syrup deaths: Government rules out toxic contamination in Madhya Pradesh, Rajasthan cases. *Deccan Herald*. 2025 Oct 3 [Cited 2025 Oct 22]. Available from: https://www.deccanherald.com/india/cough-syrup-deaths-government-rules-out-toxic-contamination-in-madhya-pradesh-rajasthan-cases-3751979
25. Bajeli-Datt K. Syrup deaths: Regulator blocks prosecution info. *New Indian Express*. 2025 Oct 26 [Cited 2025 Oct 29]. Available from: https://www.newindianexpress.com/thesundaystandard/2025/Oct/28/syrup-deaths-regulator-blocks-prosecution-info

COMMENTARY

Prescriptions of harm to prescriptions of quality: Addressing the crisis of rationality and ethics in India

ANURAG BHARGAVA

Abstract

In India, the pharmacy of the world, people still suffer poor access to essential medicines, and the impoverishing effects of out-of-pocket expenditure on purchase of medicines. Prescription audits reveal prescriptions of harm with prescriptions not aligned to treatment guidelines, with unnecessary, unsafe medicines, including irrational fixed-dose combinations that are a dominant feature of the pharmaceutical landscape in India.This situation represents a crisis of both rationality and ethics at macro, meso and micro levels represented by different institutions, and actors; and these need to be addressed. The article argues for a a unified national drug authority with transparent evidence-based approvals, removals of all irrational medicines, a stronger quality assurance system, comprehensive cost-based price regulation and improved availability of essential medicines. Prescribers need training in the concept of rational use of medicines, essential medicines and of generics, and should be subjected to regular prescription audits. It also suggests a need to widen the focus from quality of medicines alone to quality of prescription.

Keywords: *rational use, ethics, pharmaceuticals, drug policy, quality assurance, prescriptions, audits*

Introduction

Medical men do not know the drugs they use, nor their prices –

Sir Francis Bacon, *De Erroribus Medicorum* [1]

As much as seventy percent of the pharmaceuticals on the world market today are duplicative or non-essential. Large sections of the population lack access to even the most essential drugs. The limited funds available are frequently spent on ineffective, unnecessary or dangerous drugs [2].

Francis Bacon's observation seems to be true even four centuries later, with worrying implications for those who believe that public health and clinical medicine should be evidence-based (rational) and patient-centred (ethical). Neither of these points refers to the costs and consequences of the prescriptions of ineffective, unnecessary or dangerous drugs, which are catastrophic for the poor. According to estimates for the year 2011-12, out-of-pocket (OOP) payments for medicines pushed 3.09% of Indians into poverty [3]. The following experience illustrates the catastrophic consequences of these irrational prescriptions.

In 2008, a cycle rickshaw operator with Tuberculosis (TB) and severe undernutrition sought care at Jan Swasthya Sahyog's rural hospital, in Ganiyari, Chhattisgarh. He had been ill for four months, with a history of previous admission at the District hospital in Bilaspur three months earlier. He had coughed up a small amount of blood following symptoms of fever, cough and weight loss over a few weeks. Supplementary Figure 1 (available online only) shows the bill for the prescription given to him during admission for purchase of drugs from a private pharmacy, that cost more than INR 2000 for a week's therapy. This cost included INR 952 on Inj Ceftriaxone (unnecessary and possibly available in the hospital), INR 770 on Inj Pantoprazole (unnecessary), INR 44 spent on tablets of Aceclofenac and Paracetamol [a fixed dose combination (or FDC) of two non-steroidal anti-inflammatory drugs (NSAIDS)] and INR 79 on an FDC of four drugs for TB (3% of total prescription cost, all medicines that are available free of cost under the national TB programme). An FDC of two non-steroidal anti-inflammatory drugs is unsafe and irrational because it can increase the risk of severe liver injury 6-fold [4], which should be of particular concern in a setting where anti-TB drugs have liver injury as a common and serious adverse reaction. The retail prices of these unnecessary medicines were higher than some of the better-known brands, possibly an example of the nexus between some prescribers and chemists in India [5]. It is no

wonder that the patient discontinued this unaffordable care after a week, and fortunately recovered with our treatment, despite being severely ill.

Primum non nocere

Medicine has a first principle — do no harm. It is possible to do no harm if the prescriber adheres to the principles of rational use of medicines. According to the World Health Organization (WHO), rational use of medicines requires that "Patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and the community"[6]. The medicines prescribed should have an evidence base of efficacy, safety, and cost-effectiveness. The list of essential medicines, formulated by bodies like the Ministry of Health, and the WHO, is helpful in this regard, as these medicines are selected with regard to their efficacy, safety and cost-effectiveness. Further, most of these essential medicines are single-ingredient preparations, and only 6% of the 384 medicines in the National List of Essential Medicines (NLEM) 2022 are fixed dose combinations that have a clear therapeutic rationale [7]. So rational use of medicines, with a preference for essential medicines, is a powerful principle for enhancing patient outcomes. However, the evidence, from studies of prescriptions in India that follows, paints a picture that is contrary to these principles.

This article is a perspective piece on the origins of the prescriptions of harm in India that have grave consequences for people, especially the poor. It reviews the available evidence on appropriateness of prescriptions in India; analyses the problem at three levels to point to gaps that can be addressed by policies and practices; and concludes with a discussion on prescriptions of quality that would enhance the quality of care and render it cost-effective.

The triple affliction with prescriptions in India: *irrational* use of medicines, use of *irrational* medicines, and irrational *prices*

Use of medicines in a non-rational or irrational manner is a widespread phenomenon globally, and WHO estimates that more than half of all medicines are prescribed, dispensed or sold inappropriately, and that half of all patients fail to take them correctly [6]. There are various types of irrational uses of medicines. These consist of overprescribing (using antibiotics for viral infections, polypharmacy, overuse of injections), under-prescribing (not using medicines indicated as per guidelines), extravagant prescribing (use of costly medications), and inappropriate self-medication [8]. However, in India, there is a unique problem of use of irrational medicines (ie, those which lack evidence of efficacy and safety). These irrational medicines, mostly FDCs, form an unprecedented 40% of the Indian pharmaceutical market Most of these do not address any clinical needs, are of dubious value, and lack a therapeutic rationale as described in Supplementary File 1 (available online only) [9], while imposing a health and economic cost and even impeding access to essential single-ingredient medicines [10]. In the case of FDCs of NSAIDS mentioned previously, and FDCs of antibiotics to be discussed later, they pose a risk to patients as well as to the community.

The studies of prescriptions from leading teaching hospitals conducted under the Indian Council of Medical Research (ICMR) Task Force Project on Rational Use of Drugs highlight the irrational use of medicines as well as use of irrational medicines in India [11-14]. Studies show that a majority of prescriptions were incomplete in terms of dose, duration, frequency or formulation, and only 55% aligned with the guidelines for the treatment of the relevant conditions [11]. Nearly 10% had unacceptable deviations that increased the cost, the risk of adverse drug reactions, drug interactions and even treatment failure. Over half of the prescriptions had at least one medicine from outside the NLEM [13]. Overall, nearly half of these prescriptions had an FDC, many of which do not have a rationale based on efficacy or safety and can be termed irrational [12].

A study of FDCs of NSAIDS, metformin, and psychotropic drugs available in the market found that nearly 75% of NSAID FDCs were unapproved, and this proportion was even higher for FDCs of benzodiazepine/antidepressant FDCs [15]. These pose a danger to people's health and are still promoted by the pharmaceutical companies and prescribed by physicians who should know better [16]. That findings such as 50% of prescriptions of irrational FDCs were written by specialists like cardiologists and consulting physicians, and more than 80% of prescriptions were illegible is disconcerting [17, 18]. One of the most commonly used irrational FDCs carrying a significant risk of adverse effects is proton-pump inhibitors with domperidone [19].

As per WHO, rational use of medicines also implies that patients receive medicines at the lowest possible cost [6]. In India the prices of medicines vary greatly depending upon which medicines are prescribed (NLEM or non-NLEM, single-ingredient or FDC) and where they are purchased, and the patient may well receive a prescription for drugs at the highest possible cost. Pharmaceutical companies have a right to a reasonable profit, but there is clear evidence of profiteering across medicines, including in essential medicines that are under price control. The cost of 100 mg elemental iron, required for treatment for iron deficiency anaemia, can vary from INR 0.14 to 183 — a 1300-fold difference — largely due to the FDCs containing iron [3], which are exempt from price control. The maximum retail price for many such medicines in India may well be called maximum retail prizes! A previous publication describes the anarchy of medicine prices across therapeutic segments in India [20]. Atorvastatin, a commonly used medicine for the prevention of recurrent stroke or heart attacks, is under price control in India with a ceiling price of INR 12.78 *per tablet* of 20 mg, recommended by the National Pharmaceutical Pricing Authority (NPPA); while its cost on the Jan Aushadhi website was INR 11.35 *for 10 tablets*. That amounts to the

NPPA ceiling price being 10 times the Jan Aushadhi selling price, and this anomaly is due to the fact that as per the current policy, the ceiling price of even essential medicines is not determined by the cost of manufacture but by a market-based mechanism based on an average of retail prices of leading brands. Other factors inflate retail prices. In a study across teaching hospitals, the price of drugs for cardiovascular risk factors like hypertension and diabetes prescribed under branded names was 2-8 times higher than the same drugs prescribed by its generic name. The difference between a generic NLEM and a branded non-NLEM medicine was up to 22 times higher [21].

Analysing and addressing the crisis of rationality and ethics underlying prescriptions in India

The crisis of rationality and ethics in prescriptions is interlinked and generated at multiple levels of policies, procedures and practice. A prescription that is rational but consists of costlier choices that are thrust onto the patient is violative of the ethical principles of beneficence, autonomy, and non-maleficence. At a systemic level, a pharmaceutical policy that allows irrational as well as unapproved FDCs to be in the market, or a pricing policy that allows a 10-fold variation in prices, is also violative of rationality and public health ethics.

To prevent prescriptions of harm it is necessary to examine rationality and ethics at the individual level and at the systemic levels of policies, institutions and their practices which influence the context in which prescriptions are written and permitted by the system. Proposed below are three levels of analysis and action:

1. The macro level consists of the national health and pharmaceutical policy; the organisation and functioning of the drug regulatory system at the central and state levels, and the functioning of the healthcare system.

2. The meso level consists of the pharmaceutical sector and the educational-professional-service complex. It includes manufacturing, pricing and promotional practices, the medical institutions, the regulatory bodies, the professional associations, the hospitals, polyclinics and their affiliated pharmacies and chemists.

3. The micro level consists of healthcare providers and their patients in an encounter that may take place in the public or private sector, in clinics or hospitals.

The major focus of analysis and suggested action in this piece is on the macro and meso levels as these have a profound influence on practice at the micro level. On the other hand, only exhorting prescribers to change their behaviour is unlikely to be productive without implementation of a policy and regulatory framework ensuring availability, affordability and quality of medicines and strengthened systems of training and audit.

The macro-level policy: regulatory systems at central and state levels

There are challenges to rationality and ethics at the macro level, which create and perpetuate the environment that fosters irrational medicines and irrational prescriptions. A comprehensive national drug policy should address all components involved in the processes from drug approval to its dispensing, as shown in Supplementary Figure 2 (available online only), and promote the core interventions required for rational use of drugs [22].

A fragmented policy and drug authority, and weak regulation

The progress in achieving availability, affordability and appropriate use of medicines in India has been hampered by the lack of a cohesive policy and implementation framework. Since the 1970s, various committees have underlined the need for a unified approach to drug regulation with the creation of a National Drug Authority. However, multiple regulatory agencies still exist. The Central Drugs Standards Control Organisation (CDSCO), under the Ministry of Health and Family Welfare, oversees approval, imports, licensing, and manufacture of drugs and devices. The NPPA, under the Ministry of Chemicals and Fertilisers, is entrusted with ensuring the availability of medicines and regulating drug prices.

The CDSCO and NPPA have a narrow focus on implementation of the Drugs and Cosmetics Act, 1940 (DCA, 1940) for the CDSCO, and the Drug Price Control Order (DPCO), 2013, for the NPPA. The CDSCO does not administer what is not mentioned in the DCA,1940, eg, the conduct of clinical trials before the year 2015. Unethical practices in clinical trials went unnoticed and unpunished since these did not fall within the DCA's purview. Similarly, NPPA focuses largely on the pricing of medicines in DPCO, which comprises less than 20% of the market [23]. In a federal framework, the state drug control organisations are governed by the Drugs and Cosmetics Act and primarily responsible for licences and approvals for drug manufacturing units, pharmacies, quality control and surveillance, enforcement of legal actions, and coordination with the CDSCO for enforcement of the Act nationwide.

A detailed evaluation of the functioning of the CDSCO was undertaken by the Parliamentary Standing Committee (PSC) of the Ministry of Health and Welfare in its 59th report, where it stated "The Committee is of the firm opinion that most of the ills besetting the system of drugs regulation in India are mainly due to the skewed priorities and perceptions of CDSCO. The Committee recommends that the Mission Statement of CDSCO be formulated forthwith to convey in very unambiguous terms that the organization is solely meant for public health." [24]

The inspection of pharmaceutical manufacturing facilities, the testing of drug quality, and the inspection of chemists

are all critical components of the drug regulatory system, but these continue to be undermined by understaffing, and the inadequate number and quality of drug testing services [25]. This undermines prescriber confidence in the products in the market while creating tragedies like that of diethylene glycol [26]. Schedule M of the DCA, 1940, mandates Good Manufacturing Practices (GMP), and recent revisions align it with WHO-GMP standards. If implemented as per the norms and the deadline of December 31, 2025, it would improve the quality of drug manufacturing in India.

The lack of a rigorous, transparent, evidence-based approval process

Any professionally run regulatory agency follows rigorous and transparent processes for evaluation and approval of new drugs, along with the provision of full product information, and prescribing and labelling information, and the United States Food and Drug Administration (US FDA) and Medicines and Healthcare products Regulatory Agency (MHRA) in the UK are good examples of this. The documents on the CDSCO website for approval of new drugs merely mention the date of approval along with the indication. In some cases, like the combination of Ibuprofen and Paracetamol, even the indication is missing. CDSCO does not provide the documents related to the evidence underlying its decision.

The PSC report noted numerous anomalies in the drug approval process. It scrutinised a random sample of 42 drugs (of 2167 drugs) approved by the CDSCO from 2001 to 2010, and found approval of unsafe drugs, irrational FDCs of antibiotics and NSAIDs that had no regulatory approval in any other part of the world; waiver of clinical trials for new drugs; non-review of applications in cases where such review was necessary, as well as concerns on the quality of expert review to the CDSCO. "For some drugs, which included FDCs, the decision to waive off trials, advice of experts was taken solely by the non-medical staff of CDSCO on their own." It also noted that "a review of the opinions submitted by the experts on various drugs shows that an overwhelming majority are recommendations based on personal perception without giving any hard scientific evidence or data" [24: p17]. It also noted with surprise that the qualification for the post of the Drug Controller General of India (DCGI) was merely B Pharm and "experience in the manufacture or testing of drugs or enforcement of the provisions of the Drugs and Cosmetics Act for a minimum period of 5 years"[24: p 6]; and that "The Committee is of the view that it is not very rational to give powers to a graduate in pharmacy, who does not have any clinical or research experience to decide the kinds of drugs that can be prescribed by superspecialists in clinical medicine…"[24: p 8].

The remarkable proliferation of irrational FDCs in India is due to the lack of an evidence-based process followed by the CDSCO. Supplementary Table (available online only) shows some irrational FDCs it has approved with their indications, and the regulatory approval in other countries. For example, the CDSCO's indication for the irrational combination of doxycycline and lactobacillus reads thus, "For adult patients prone to intrabdominal bacterial infection & antibiotic-associated diarrhoea" [27]. This does not even specify for which infections this combination should be used. CDSCO has approved 22 different FDCs for "treatment of diabetic neuropathy", including formulations with multiple vitamins without evidence of efficacy. Once a particular FDC enters the market, it sets the precedent for many such irrational FDCs, which are often used for a wide variety of conditions, thus legitimising irrationality. Over years with heavy drug promotion, it shapes irrational therapeutic choices. These irrational FDCs are a ruse to avoid price control which applied only to single-ingredient medicines and rational FDCs mentioned in the NLEM. So, the CDSCO is responsible for both approval of unscientific medicines and undermining price regulation.

The proliferation of irrational medicines is also due to the apathetic attitude of the CDSCO to violations of the provisions of the Drugs and Cosmetics Act regarding FDCs, and the inability or reluctance of the CDSCO to enforce these provisions. After 1999, the Drugs Rules, 1945, clearly include the new FDCs in the definition of a new drug under Rule 122 E that requires approval from CDSCO [28]. Under the New Drugs and Clinical Trials Rules 2019 the manufacturers were required to provide evidence for any "FDCs of two or more drugs, individually approved earlier for certain claims, which are now proposed to be combined for the first time in a fixed ratio, or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims viz indications, dosage, dosage form and route of administration"[29] However, the State Licensing Authorities continued to ignore this rule and get the CDSCO approval for new FDCs. The following extraordinary FDC with seven drugs was licensed by state licensing agencies and finally banned by the CDSCO in 2007: Paracetamol + Diclofenac + Amoxicillin + Cloxacillin + Lactobacillus + Pantoprazole + Serratiopeptidase. However, this FDC, one of 294 such irrational FDCs licensed by state authorities and not approved by CDSCO was banned only in 2019, delayed due to examination by a committee and litigation by companies [30].

There has been a succession of committees that have been appointed to address the issue of irrational FDCs, with the latest being the Prof Kokate Committee. But these committees examine each FDC individually, without applying broader principles of evidence-based medicine or pharmacological principles These FDCs do not exist in any textbook, are not recommended in any guideline, and are not used in any developed country. So, while a committee could ban any combination of classes of drugs as irrational, it examines an FDC with a drug X from class A with drug Y from another class of drugs and may ban it, only to have newer FDCs emerge of some different combination of drugs.

The CDSCO also has the power under the provisions of Section 26A of the Act to itself ban any drug or FDC that does not have the therapeutic value claimed. It also has powers under Section 33P to give directions to state authorities to withdraw the licenses of FDCs granted without the DCGI's approval, but rarely exercises this [26]. The approval of a plethora of drugs and formulations that do not have therapeutic justification, increase cost and pose a risk to people, is violative of ethics. Irrational FDCs have been withdrawn largely due to the efforts of activists filing complaints or public interest litigations, which drag on for years.

A regulatory agency should, in the interest of public health, provide periodic updates on medicines, highlight safety considerations as black box warnings, and alert the public to any market-related actions like drug withdrawals. For example, Montelukast, a drug used for the treatment of allergic rhinitis and bronchial asthma, has been linked to serious neuropsychiatric side effects, especially in younger individuals. Eighty-two cases of completed suicides linked to Montelukast and its generic versions were reported to the FDA's adverse event database from 1998 to 2019 [31,32]. The websites of USFDA and MHRA and copies of the British National Formulary, carry this warning, with information about safer alternatives., There is no similar advisory in India issued by the CDSCO. In India, the combination of Levocetrizine and Montelukast is widely used not just for allergic rhinitis, but also for a common cold. Finally, a regulatory agency should be cognisant of the possibility of dispensing errors due to look-alike and sound-alike medicines. There is no comprehensive registry of brand names, and the market is replete with instances of such medicines that can have serious consequences [33].

Continued challenges in the availability and affordability of medicines

The National Health Policy 2017 did not address the low availability of essential medicines in public health facilities [34] and the availability of essential medicines continues to be much lower than the 80% level recommended by WHO [35]. A systematic review found that 17-51% of essential medicines were available across states; Tamil Nadu performed best in this regard [36].

The NPPA regulates the affordability of medicines by implementing the price control order. However, the Drug Price Control is only partial, as it covers only those medicines (and their specific formulations) mentioned in the NLEM, which are referred to as scheduled formulations. Medicines and formulations outside the NLEM are regarded as non-scheduled formulations. Only 14% of the medicines in the market by value and 25% by volume are mentioned in the NLEM [37]. Also, prescriptions are not aligned to the NLEM, either in the private or even the public sector, as alluded to earlier [13]. Strangely, price control in India applies only to the strengths and formulations mentioned for the particular drug under the NLEM. So, price control applies only to Paracetamol injection of 150 mg/ml, which is INR 4.04 excluding taxes as regulated by NPPA [38]. However, a different formulation, such as 1000 mg paracetamol in 100 ml saline, escapes price control and can be sold at INR 510, a retail price more than 30-fold higher [39].

The current mechanism of price control in India has no rational relation to the cost of production of medicines in India. Before 2012, the selling price was based on adding a markup to the product's unit cost, 100%-150% for scheduled and non-scheduled formulations. After 2012, the government switched to market-based pricing, where a simple average price of the leading brands with more than 1% market share was used to determine the ceiling price. The information on market share is sourced from a database that is not accessible to the public. This opaque process has led to a disconnect between the retail price and the cost of manufacture and post-manufacturing expenses, which is apparent when we compare the price of medicines in Jan Aushadhi stores and the ceiling price of the NPPA. Even if one assumes that Jan Aushadhi prices are the cost price of manufacturing, the ceiling price determined by the average price of leading brands is many times that price. Patients end up spending in one year what they should be spending in five or even 10 years. A monograph on price regulation in India concluded that the current design of price regulation based on market mechanisms was ineffective, and recommended frequent revision of the NLEM, expanding its ambit to include all dosages and their fixed dose combinations, and improving implementation and enforcement activities [40].

To conclude this section, a reform of the national drug policy and the drug regulatory authority is urgently called for to ensure access to essential medicines, their affordability, quality and rational use. There is WHO guidance on how to develop and implement a national drug policy and drug regulatory system [22].

The meso level: Pharmaceutical companies and medical institutions

Pharmaceutical companies: Rational abroad and irrational at home

Pharmaceutical companies have double standards with regard to both generics (unbranded drugs) and FDCs. Companies export unbranded single-ingredient pharmaceutical products to developed markets abroad. In the US, 91% of prescriptions are filled by generic medicines, of which 87% are unbranded generics [41]. In India, as seen in Supplementary File 2 (available online only), 87% of the market is of branded generics [42].

At home, they claim superiority for their branded products, and market irrational FDCs that they never export. Multinational companies manufacture and market medicines in India that have been banned in their country of origin, or market FDCs that are not promoted abroad.

Deanxit, a contested FDC product containing flupentixol and melitracen, manufactured by Lundbeck, a Danish company, was approved without supporting data in India, while it was prohibited for sale in Denmark. It was banned in India in 2013, but even 10 years later, there was evidence of several Indian companies making the same combination with impunity [43].

The particular hazard of irrational antibiotic FDCs

In an era of rising antimicrobial resistance (AMR), it is distressing to note that among the most irrational FDCs made in India are antibiotics. A 2020 study revealed that 90% of antibiotic FDCs in India were irrational, and two-thirds were unapproved or banned and include oral and injectables [44]. The WHO has suggested an Access, Watch and Reserve antibiotics (AWaRE) classification for antibiotics to curb their indiscriminate use. In India pharmaceutical companies manufacture antibiotic FDCs of Watch group like ceftriaxone, cefuroxime, cefixime with beta-lactamase inhibitors like sulbactam, tazobactam, and clavulanic acid. A number of microbiologists, pharmacologists, and public health professionals have drawn attention to the fact that these lack any supportive in-vitro data, including pharmacokinetic/pharmacodynamic studies, or properly conducted clinical studies supporting the combination [44-47]. None of these FDCs are exported to developed countries.

A recent aggressively marketed antibiotic brand, Elores, combines an irrational combination of ceftriaxone with sulbactam with a drug like ethylene diamine tetra-acetic acid (EDTA), which does not appear in any textbook, guideline or approved list of any established regulatory agency [45]. The website makes claims of efficacy against highly drug-resistant bacteria and mentions Elores as "a novel patented Antibiotic Adjuvant Entity containing a beta-lactam antibiotic, a beta-lactamase inhibitor and an Antibiotic Resistance Breaker (ARB)" [48]. A recent trial concluded that this combination was inferior to standard of care in urinary tract infections caused by metallo-beta-lactamase producing enterobacterales with an unacceptable difference in cure rates [49]. The claims of the company regarding the efficacy of ceftriaxone-sulbactam-EDTA are misleading and can be dangerous if believed by practitioners who are faced with a patient with a drug-resistant gram-negative infection.

Drug promotion: The 3 Cs, and myth-making around brands and generics

The tried and tested 3 Cs of marketing of medicines in India have been described succinctly by Dr CM Gulhati as follows: "Convince, if possible, Confuse if necessary, and Corrupt if nothing else works" [50]. Studies have documented promotional practices like misleading information, incentives and unethical trade practices [5].

The promotional practices of pharma companies are focused on marketing FDCs over single-ingredient preparations, branded non-NLEM drugs outside price control over NLEM medicines, and costlier medicines over cost-effective ones.

Doctors in India have genuine concerns around the quality of medicines, given the multiplicity of manufacturers, and the functioning of the drug regulatory system that does not inspire confidence. Pharma companies exploit this concern where the doctor believes in the brand and its often-high price as a surrogate for quality.

Pharmaceutical companies also spread misinformation about the concept of generics to promote the sales of their brands. The WHO defines generic medicines as "a pharmaceutical product, usually intended to be interchangeable with the innovator product, which is usually manufactured without a license from the innovator company and marketed after the expiry of the patent or other exclusivity rights" [51]. The innovator product is usually termed as a brand-name medicine. Thus, a generic refers to an off-patent product that is therapeutically equivalent to the innovator product and can be marketed either in the generic name or under a brand name as a "branded generic" [Supplementary Figure 3 (available online only)]. Some regulatory agencies, like the US FDA, require proof of bioequivalence, but this is not a uniform requirement across the world. According to the WHO definition, almost the entire pharmaceutical market in India would qualify as a generics market, marketing predominantly branded generics. This WHO definition does not distinguish between unbranded and branded generics.

In India, the word "generic" refers to the nomenclature under which the medicine is marketed. All medicines in India, including brand-name medicines, have to have the generic name. In this sense, generics refer to medicines marketed under only the non-proprietary /generic name, and these are a few medicines available mostly in government health facilities and the Jan Aushadhi shops.

While India is largely a market of branded generics, the pharmaceutical industry has further confused the issue with a classification based on its marketing practices, into so-called "branded medicines" and "branded generics" which has no legal or pharmacological basis, as all are supposed to conform to the same standards [Supplementary Figure 3 (available online only)]. The branded generics that are promoted only to doctors by medical representatives carry a cost of marketing and are promoted as so-called "branded medicines" (which are actually branded generics as they are all out of patent and are not innovator brands), usually for chronic diseases like diabetes and cardiovascular diseases. The companies sell other branded generics directly to distributors/chemists/hospitals without doctor promotion. These are termed the so-called "branded generics" or trade generics which have similar retail prices to branded medicines; but provide high margins for retailers or hospital stores who push them in case of acute conditions (antibiotics, pain-killers). While generics abroad are therapeutically equivalent products whose quality is assured by the regulator; in India, the weaker regulatory system

forces even rational prescribers to place their trust in companies or brands, despite their higher prices.

Many leading companies unknown to the doctors' market both "branded" medicines and "branded generics". A study compared *price* and *quality* of "branded" and "branded generics" manufactured by the *same* pharmaceutical company in India [52]. The margin for the retailer on branded medicines was 25-30%, but for the branded generic version of the same company it was between 201 and 1016%. The quality of branded generics was the same as for the branded version [52]. Doctors who fall to the proxy of price for quality never know that the actual cost for the manufacturer is much lower than the maximum retail price indicates. The same company that offers a 357% margin to the retailer in the case of the so-called generic is not offering any lower price to consumers [52].

Medical colleges, professional associations and professional bodies and rationality and ethics

Currently, pharmacology trains students in the rational and cost-effective use of medicines and in writing a rational prescription. A study, however, showed that more than half of first-year post-graduates felt that they had insufficient training in their undergraduate course to prescribe safely and rationally [53]. The National Medical Commission (NMC) curriculum does include the concept of the NLEM, but the awareness is low [54]. Young doctors wanted more training on issues of brand-name and generic-named drugs, and FDCs (rational or irrational) [53]. 81% of residents in a teaching hospital could not assess the rationality of an FDC [55]. These issues need to be addressed, as otherwise, prescribing practices are influenced by peer practices that may not be evidence-based or cost-effective. Prescription audits should become routine in our medical colleges and lead to corrective action.

The medical representatives of companies are a major source of information about new medicines for doctors, and it is imperative that they are trained to critically evaluate their claims that are often exaggerated or misleading. Pharma companies are a major source of sponsorship for continuing medical education (CMEs) events of colleges and professional associations. A direction by the NMC prohibiting such sponsorship in August 2023 evoked a backlash and was later withdrawn. Across the world, there is a general agreement that the content of CMEs should be independent and free from undue influence by the pharmaceutical industry. There are instances in CMEs in India where the speakers often use slides provided by the pharma companies with their logos.

In 2023, the NMC exhorted all medical professionals in India to prescribe medicines under their generic names and ensure rational use of drugs. This may have been a well-meaning injunction, but it is not enforceable for the following reasons. If the government is providing unbranded generics, then this directive makes sense. If the state governments can assure the availability and quality of these medicines, they could, in addition, prohibit prescriptions for pharmacies. If the injunction is for doctors in the private sector, then it is unrealistic, as medicines under generic names are virtually non-existent in the retail market. The presence of unqualified dispensers and poor-quality pharmacy training creates a situation where the dispensers do not even understand generic names. Doctors too have reservations about the chemists' substituting brands which give them higher margins. If the injunction could have specified that private practitioners can mention the brand name or the name of the company in brackets, it can prevent this substitution. In developed countries with stringent quality assurance, generic substitution by the pharmacist has a legal sanction. But that is not the case in India.

In this context, the Jan Aushadhi scheme that was launched in 2008, and which has undergone expansion in recent years to about 17,000 outlets, offers an opportunity for patients to access good quality generic medicines and surgical consumables, at prices that are 50% to 80% cheaper than branded medicines, if they are advised to do so by those who treat them [56]. Medicines at these outlets are procured only from suppliers certified for WHO–Good Manufacturing Practices (WHO-GMP). Each batch of drugs supplied under the scheme is tested at laboratories accredited by the National Accreditation Board for Testing and Calibration Laboratories (NABL). Only after the medicines pass the quality tests, are they dispatched to Jan Aushadhi Kendras. Quality audit of the facilities of vendors is routinely done by the Pharmaceuticals and Medical Devices Bureau of India [56].

The micro level: Enabling rationality and ethics at the level of the patient and the individual prescriber

Despite all the obstacles and stumbling blocks, the micro level is the place where the practitioner can make an immediate difference by being rational and ethical. If patients perceive that doctors are acting in their interest, it would address the trust deficit that is emerging in the doctor-patient relationship in India. A doctor can be expected to practise rational and ethical medicine only in a system that is rational and ethical. It is futile to expect the prescriber to be rational and evidence-based if they have been inadequately trained in these aspects; if rational and evidence-based medicines are either not available in government facilities, or what is available is not rational and evidence-based. A prescriber cannot prescribe cost-effective generic medicines if their hospital stocks only expensive brands and coerces patients to buy medicines only from their pharmacies. When prescribers prescribe more expensive brands concerned about the quality of medicines, then it is the regulator's role to ensure that all drugs in the market, regardless of manufacturer, conform to the same standards, so that prescribers do not use the company or the price as a surrogate for quality.

Transiting from concerns about the quality of medicines to the quality of prescriptions

While there is a lot of discussion around the quality of medicines in India, there is not enough discussion on the quality of diagnosis and on prescriptions. It's time to focus on prescription quality that is inclusive of quality of medicines as well as rationality and ethics. The elements of such a prescription should include elements of rationality (indication, efficacy, safety) and elements of ethics — of beneficence (efficacy), non-maleficence (safety), autonomy (empowering patients in their understanding of disease and its treatment, offering a range of options to source medicines) and justice (keeping costs low). The WHO has suggested a six-step guide for prescribing, which is a useful resource for rational prescribers, and the following suggestion on a prescription of quality builds on this guide with additional elements [57]. We need to have a regular system of prescription audits in both the public and private sector. The NMC has directed all medical colleges to establish a sub-committee under the Drug and Therapeutics Committee for monitoring prescription practices [58].

The features of a prescription of quality

1. Necessity: Does the patient really need this drug?
2. Efficacy: Is the use of medicines supported by evidence from randomised controlled trials or recommendations of evidence-informed guidelines? Does the prescription include advice on efficacious non-pharmacological interventions, like lifestyle modification?
3. Safety: Is the prescription safe for this particular person in view of age, coexisting medical conditions, and potential drug interactions?
4. Cost-effectiveness: Is the prescription affordable for this person, and could we avoid or reduce costs by prescribing essential medicines available in a public health facility or advising purchase from a Jan Aushadhi Kendra?
5. Information, comprehension, and shared decision making: Is the prescription legible, and does the person understand the disease, and its treatment with regard to dose, schedule, side-effects. Can the patient "teach-back" the prescription to the prescriber to communicate their understanding [59]? Can the patient demonstrate modes of administration like injection of insulin, use of inhalers?

Conclusion and the way forward

The current situation in India with regard to rationality and ethics in the access, price, quality and use of medicines is not tenable. Provision of essential medicines continues to be suboptimal, while millions are impoverished by purchase of medicines that are often unnecessary, ineffective, unsafe, or unnecessarily expensive. This calls out for a revised national drug policy aligned to the national health policy, with a unified and strengthened drug regulatory authority and quality assurance system, supported by new legislation, that ensures access to essential and affordable medicines of assured quality, that are promoted ethically, used rationally, and dispensed safely. All medicines need to be approved by a transparent, evidence-based approval process with full disclosure of prescribing information. The menace of existing irrational FDCs needs to be removed by better coordination with state licensing authorities and invoking sections of the existing laws. Price regulation can be comprehensive and cost-based to curb profiteering, while maintaining profitability and growth of the pharmaceutical sector. Medical institutions and professional bodies need to be accountable for the quality and safety of prescriptions and these need to be ensured by regular prescription audits.

Note: *The last three references in the reference list are cited in the Supplementary File 2 and the Supplementary Table.*

Author: Anurag Bhargava (anuragb17@gmail.com, https://orcid.org/0000-0001-7187-8759), Department of Medicine, Kasturba Medical College Mangalore, Manipal Academy of Higher Education, Manipal, INDIA.

Conflict of Interest: None declared **Funding:** None

Author's note: 1) This article is dedicated to the memory of Dr CM Gulhati in acknowledgement of his outstanding and inspiring services to the nation to make the practice of medicine and the use of medicines rational and ethical; 2) The views, thoughts, and opinions expressed in the article belong solely to the author. They do not reflect the opinions or official position of the author's institution.

Acknowledgments: I wish to gratefully acknowledge the detailed comments of Dr Madhavi Bhargava on the manuscript.

To cite: Bhargava A. Prescriptions of harm to prescriptions of quality: Addressing the crisis of rationality and ethics in India. *Indian J Med Ethics.* 2026 Apr-Jun; 11(2) NS: 121-130. DOI: 10.20529/IJME.2026.028

Submission received: March 11, 2026

Submission accepted: April 16, 2026

Theme Editors: Sandhya Srinivasan, Veena Johari

Peer Reviewers: Jaya Ranjalkar, Vijayaprasad Gopichandran, George Thomas

References

1. McDonald P. Oxford Dictionary of Medical Quotations. 1st ed: Oxford University Press; 2004. 212 p.
2. Quick JD, Hogerzeil HV, Rankin JR, Dukes MNG, Laing, R et al. *Managing drug supply: the selection, procurement, distribution, and use of pharmaceuticals. Management Sciences for Health in Collaboration with the World Health Organization.* 2nd ed, revised and edited. Kumarian Press; 1997. 816 p.
3. Selvaraj S, Farooqui HH, Karan A. Quantifying the financial burden of households' out-of-pocket payments on medicines in India: a repeated cross-sectional analysis of National Sample Survey data, 1994-2014. *BMJ Open.* 2018;8(5):e018020. https://doi.org/10.1136/bmjopen-2017-018020
4. Clinard F, Sgro C, Bardou M, Hillon P, Dumas M, Kreft-Jais C, et al. Association between concomitant use of several systemic NSAIDs and an excess risk of adverse drug reaction. A case/non-case study from the French Pharmacovigilance system database. *Eur J Clin Pharmacol.* 2004;60(4):279-83. https://doi.org/10.1007/s00228-004-0761-0
5. Roy N, Madhiwalla N, Pai SA. Drug promotional practices in Mumbai: a qualitative study. *Indian J Med Ethics.* 2007 Apr-Jun;4(2):57-61. https://doi.org/10.20529/ijme.2007.020
6. World Health Organization. Rational use. Geneva: WHO; 2026 [Cited 2026 April 1]. Available from: https://www.who.int/teams/health-

product-policy-and-standards/medicines-selection-ip-and-affordability/medicines-policy/rational-use
7. Ministry of Health and Family Welfare, Govt of India. National List of Essential Medicines 2022. New Delhi:MoHFW;2022[Cited 2026 Jan 14]. Available from: https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadConsumer/nlem2022.pdf
8. Ofori-Asenso R, Agyeman AA. Irrational Use of Medicines—A Summary of Key Concepts. *Pharmacy (Basel)*. 2016;4(4):35. https://doi.org/10.3390/pharmacy4040035
9. Bhargava A. Dubious rather than spurious drugs: India's real drug problem. *Health Action*. 2009(September):4-7.
10. Bhargava A, Kalantri S. The crisis in access to essential medicines in India: key issues which call for action. *Indian J Med Ethics*. 2013;10(2): 86-95. https://doi.org/10.20529/IJME.2013.028
11. Shetty Y, Kamat S, Tripathi R, Parmar U, Jhaj R, Banerjee A, et al. Evaluation of prescriptions from tertiary care hospitals across India for deviations from treatment guidelines & their potential consequences. *Indian J Med Res*. 2024 Feb 1;159(2):130-41. https://doi.org/10.4103/ijmr.ijmr_2309_22
12. Ranjalkar J, Jhaj R, Chandy SJ, Ight HR, Chugh PK, Tripathi CD, et al. Usage Pattern of Fixed-dose Combinations at ICMR Network of Rational Use of Medicine Centres across India: Recommendations for Policymakers and Prescribers. *J Assoc Physicians India*. 2023 Feb;71(2): 11-2. https://doi.org/10.5005/japi-11001-0175
13. Jhaj R, Banerjee A, Kshirsagar NA, Sadasivam B, Chandy SJ, Bright HR, et al. Use of drugs not listed in the National List of Essential Medicines: Findings from a prescription analysis by the Indian Council of Medical Research-Rational Use of Medicines Centres Network in tertiary care hospitals across India. *Indian J Pharmacol*. 2022 Nov-Dec;54(6):407-16. https://doi.org/10.4103/ijp.ijp_878_21
14. Shukla AK, Khasbage SU, Jhaj R, Sadasivam B, Cherian JJ, Chugh PK, et al. Prescribing trends of fixed-dose combination of domperidone and proton-pump inhibitor across tertiary care centers in India, is the combination rational? *Indian J Pharmacol*. 2025 May;57(3):159-65. https://doi.org/10.4103/ijp.ijp_744_23
15. McGettigan P, Roderick P, Mahajan R, Kadam A, Pollock AM. Use of Fixed Dose Combination (FDC) Drugs in India: Central Regulatory Approval and Sales of FDCs Containing Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), Metformin, or Psychotropic Drugs. *PLoS Med*. 2015 May;12(5):e1001826; discussion e. 1001826. https://doi.org/10.1371/journal.pmed.1001826
16. Solanki MS, Banwari G. Irrational fixed dose combinations of psychotropic drugs in India: Cause of concern. *Indian J Pharmacol*. 2016 Jul-Aug;48(4):468-9. https://doi.org/10.4103/0253-7613.186192
17. Bhaskarabhatla A, Chatterjee C. The role of physicians in prescribing irrational fixed-dose combination medicines in India. *Soc Sci Med*. 2017 Feb;174:179-87. https://doi.org/10.1016/j.socscimed.2016.12.022
18. Shelat PR, Kumbar SK. Analysis of Out Door Patients' Prescriptions According to World Health Organization (WHO) Prescribing Indicators Among Private Hospitals in Western India. *J Clin Diagn Res*. 2015 Mar; 9(3):Fc01-4. https://doi.org/10.7860/jcdr/2015/12724.5632
19. Maideen NMP. Adverse Effects Associated with Long-Term Use of Proton Pump Inhibitors. Chonnam *Med J*. 2023 May;59(2):115-27. https://doi.org/10.4068/cmj.2023.59.2.115
20. Srinivasan S, Bhargava A, editors. *Impoverishing the Poor: Pharmaceuticals and Drug Pricing in India*. Vadodara/Bilaspur: LOCOST/Jan Swasthya Sahyog; 2004.
21. Chugh PK, Gupta P, Wasan H, Tripathi CD, Chandy SJ, Ranjalkar J, et al. Prescription-based cost analysis of medicines for cardiovascular risk factors at Indian Council of Medical Research-Rational Use of Medicine Centre Hospitals of India. *Indian J Pharmacol*. 2024 Mar;56(2): 97-104. https://doi.org/10.4103/ijp.ijp_61_23
22. World Health Organization. How to develop and implement a national drug policy. 2nd ed. Geneva: WHO; 2001 Dec [Cited 2026 Jan 14]. Available from: https://www.who.int/publications/i/item/924154547X
23. Phadke A. Why medicines are so costly in India. The Hindu Centre for Politics and Public Policy; 2024 Dec 9[Cited 2026 Jan 14]. Available from: https://www.thehinducentre.com/the-arena/why-medicines-are-so-costly-in-india-html-version/article68950044.ece
24. Department-related Parliamentary Standing Committee on Health and Family Welfare. Fifty-ninth Report on the functioning of the Central Drugs Standard Control Organisation (CDSCO), Rajya Sabha Secretariat. May 2012 [Cited 2026 Jan 14]. Available from: https://thetruthpill.in/wp-content/uploads/2024/05/59th-Report-of-the-Parliamentary-Standing-Committee-on-Health-on-the-Functioning-of-the-CDSCO-2012.pdf
25. Krishnan V, John A. The Massive Failures of India's Drug Regulatory System. *Himal Mag*. 2025 March 12[Cited 2026 Jan 14]. Available from: https://www.himalmag.com/politics/india-pharma-regulation-drug-safety
26. Nagarajan R. DEG deaths: Why is India unable to stop them? *Indian J Med Ethics*. 2026 Apr-Jun; 11(2) NS: 117-121. https://doi.org/10.20529/ijme.2025.082
27. Central Drugs Standard Control Organization. Available from: https://cdscoonline.gov.in/CDSCO/cdscoDrugs
28. Ministry of Health and Family Welfare, Govt of India.The Drugs and Cosmetics Act 1940 , and Rules, 1945. Act No 23 of 1940. As amended up to 30th June, 2005. New Delhi: MoHFW; 2005. Available from: https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/Drugs-and-Cosmetics-Act/ 2025.
29. Central Drugs Standard Control Organization. Directorate Generate of Health Services. The New Drugs and Clinical Trials Rules, 2019 p 5. New Delhi: Ministry of Health and Family Welfare, Government of India. Available from: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTg4OA==
30. Central Drugs Standard Control Organisation, Ministry of Health and Family Welfare. Notification dated January 11, 2019, published in the Gazette of India Extraordinary. Reference. 2019.01.11_S.O. 180(E) to S.O.259(E)_Prohibition of certain FDCs appeared in the list of 294 FDCs, under Section 26A. p 35. CDSCO [Cited 2026 Jan 14]. Available from: https://cdsco.gov.in/opencms/opencms/en/Drugs/FDC/
31. US Food and Drug Administration. Transcript of the September 27, 2019 joint meeting of the Pediatric and Drug Safety and Risk Management Advisory Committees.. 2019 Sep [Cited 2026 Mar 15]. Available from: https://www.fda.gov/media/132560/download
32. Tiwaskar M, Kamdar BJ, Prabhudesai PP. Montelukast: A Scientific and Legal Review. *J Assoc Physicians India*. 2025 May;73(5):70-8. https://doi.org/10.59556/japi.73.0936
33. Neelakantan M, Sharma P, Kulkarni A. Look-alike, sound-alike (LASA) drugs in India. *Lancet Reg Health Southeast Asia*. 2024 May 16;26:100425. https://doi.org/10.1016/j.lansea.2024.100425
34. Ministry of Health and Family Welfare, Govt of India. National Health Policy 2017. New Delhi:MoHFW; 2017[Cited 2026 Jan 14]. Available from: https://nhsrcindia.org/sites/default/files/2021-07/National%20Health%20Policy%202017%20%28English%29%20.pdf
35. Prinja S, Bahuguna P, Tripathy JP, Kumar R. Availability of medicines in public sector health facilities of two North Indian States. *BMC Pharmacol Toxicol*. 2015 Dec;16:43. https://doi.org/10.1186/s40360-015-0043-8
36. Wadhwa M, Trivedi P, Raval D, Saha S, Prajapati H, Gautam R, et al. Factors Affecting the Availability and Utilization of Essential Medicines in India: A Systematic Review. *J Pharm Bioallied Sci*. 2024 Apr;16(Suppl 2):S1064-s71. https://doi.org/10.4103/jpbs.jpbs_1198_23
37. Pilla V. Explainer: How drug prices are regulated in India. *Moneycontrol*. 2019 Nov 5 [cited 2026 Apr 3]. Available from: https://www.moneycontrol.com/news/business/explainer-how-drug-prices-are-regulated-in-india-4606751.html
38. National Pharmaceutical Pricing Authority, Ministry of Chemicals and Fertilizers, Govt of India. Pharma Sahi Daam. New Delhi: NPPA; 2025[Cited 2026 Jan 15]. Available from: https://nppa.gov.in/pharma_sahi_daam
39. Current Index of Medical Specialities (CIMS): Updated Prescribers' Handbook. July 2025, Update 3. Bengaluru: CIMS Medica India Private Limited; 2025
40. Bhaskarabhatla A. *Regulating Pharmaceutical Prices in India: Policy Design, Implementation and Compliance*. Cham: Springer; 2018. p 1.
41. Center for Drug Evaluation and Research. Office of Generic Drugs 2022. Annual Report. FDA. 2024[Cited 2026 Jan 14]. Available from: https://www.fda.gov/media/165435/download
42. Market Study on the Pharmaceutical Sector in India: Key Findings and Observations. New Delhi: Competition Commission of India; 2021 Nov 18[Cited 2026 Jan 14]. Available from: https://www.cci.gov.in/economics-research/market-studies/details/19/1
43. Barnagarwala T. The story of a drug that India has failed to ban 2024. *Scroll*. Updated 2024 Jan 4[Cited 2026 Apr 3]. Available from: https://scroll.in/article/1061277/the-story-of-a-drug-that-india-has-failed-to-ban
44. Anand P, Kaur N, Verma V, Shafiq N, Malhotra S. Assessment of rationality of available fixed dose combinations of antibiotics in India. *Expert Rev Anti Infect Ther*. 2022;20(5):797-808. https://doi.org/10.1080/14787210.2022.2015324
45. Palwe S, Veeraraghavan B, Periasamy H, Khobragade K, Kharat AS.

Unorthodox Parenteral β-Lactam and β-Lactamase Inhibitor Combinations: Flouting Antimicrobial Stewardship and Compromising Patient Care. *Antimicrob Agents Chemother.* 2020;64(5). https://doi.org/10.1128/aac.00168-20
46. Ahmad A, Khan MU, Balkrishnan R. Fixed-dose combination antibiotics in India: global perspectives. *Lancet Glob Health.* 2016;4(8):e521. https://doi.org/10.1016/s2214-109x(16)30093-6
47. Brhlikova P, Mehta A, McGettigan P, Pollock AM, Roderick P, Farooqui HH. Regulatory enforcement of the marketing of fixed-dose combinations in India: a case study of systemic antibiotics. *J Pharm Policy Pract.* 2023;16(1):139. https://doi.org/10.1186/s40545-023-00644-y
48. Venus Remedies - Indian research driven pharmaceutical company. Elores. Venus Remedies website. [Cited 2026 Jan 15]. Available from: https://venusremedies.com/elores
49. Samantaray S, Kumar D, Bohra GK, Meena DS, Agarwal A, Chaudhary GR, et al. 381. Effect of Ceftriaxone+sulbactam+disodium EDTA Combination in Treatment of Complicated Urinary Tract Infections Caused by Metallo Beta-lactamase Producing Enterobacterales: An Open Label Randomized Controlled Trial. *Open Forum Infect Dis.* 2023;10(Supplement_2). https://doi.org/10.1093/ofid/ofad500.451
50. Gulhati CM. Marketing of medicines in India. *BMJ.* 2004 Apr 3; 328(7443):778-9. https://doi.org/10.1136/bmj.328.7443.778
51. World Health Organization. Expert Committee on Specifications for Pharmaceutical Preparations, Fifty Second Report. Vol 1010 (1). Geneva: WHO; 2018 [Cited 2026 Jan 14]. Available from: https://www.who.int/publications/b/31079
52. Singal GL, Nanda A, Kotwani A. A comparative evaluation of price and quality of some branded versus branded-generic medicines of the same manufacturer in India. *Indian J Pharmacol.* 2011 Apr;43(2):131-6. https://doi.org/10.4103/0253-7613.77344
53. Upadhyaya P, Seth V, Sharma M, Ahmed M, Moghe VV, Khan ZY, et al. Prescribing knowledge in the light of undergraduate clinical pharmacology and therapeutics teaching in India: views of first-year postgraduate students. *Adv Med Educ Pract.* 2012;3:47-53. https://doi.org/10.2147/amep.s31726
54. Jani CK, Agrawal A. Acquaintance of medical students with the National List of Essential Medicines. *Nat J Physiol Pharm Pharmacol.* 2024[Cited 2026 Jan 15];14(9):1773-6. Available from: https://www.bibliomed.org/gotodoi.php?mno=194280&gdoi=10.5455/njppp.2024.14.03127202424032024
55. Goswami N, Gandhi A, Patel P, Dikshit R. An evaluation of knowledge, attitude and practices about prescribing fixed dose combinations among resident doctors. *Perspect Clin Res.* 2013;4(2): 13. https://doi.org/10.4103/2229-3485.111797
56. Press Information Bureau, Union Ministry of Chemicals and Fertilisers. The Government launched the Pradhan Mantri Bhartiya Janaushadhi Pariyojana scheme to make quality generic medicines available at affordable prices to all. New Delhi: PIB; 2025 Jul 25 [Cited 2026 March 2]. Available from: https://www.pib.gov.in/PressReleasePage.aspx?PRID=2148570&reg=3&lang=2
57. de Vries TPGM, Henning RH, Hogerzeil HV, Fresle DA, et al. Guide to Good Prescribing: a practical manual. Geneva: World Health Organization; 1994 [Cited 2026 Jan 14]. Available from: https://iris.who.int/server/api/core/bitstreams/4e79820f-9519-4687-91f6-38b89f96d334/content
58. Post Graduate Medical Education Board (PGMEB). Public Notice no. N-P016(11)2/2023 dated 11.12.2025. Establishment of Sub-Committee under the Drugs and Therapeutics Committee (DTC) for Monitoring of Prescription Practices and Inclusion of "Importance of Legible and Clear Handwriting in Medical Prescriptions" in the curriculum - reg. [Cited 2026 Jan 15]. Available from: https://www.nmc.org.in/MCIRest/open/getDocument?path=/Documents/Public/Portal/LatestNews/Upload.pdf
59. Bond C, Blenkinsopp A, Raynor DK. Prescribing and partnership with patients. *Br J Clin Pharmacol.* 2012 Oct;74(4):581-8. https://doi.org/10.1111/j.1365-2125.2012.04330.x
60. Selvaraj S, Karan K A, Srivastava S, Bhan N, & Mukhopadhyay I. India health system review. New Delhi: World Health Organization, Regional Office for South-East Asia; 2022
61. Veeraraghavan B, Bakthavatchalam YD, Kandasamy S, Iyadurai R. Clinical efficacy of novel combinations of older beta-lactam and beta-lactamase inhibitors: Where are the evidences? *Indian J Med Microbiol.* 2022;40(2):179-81.
62. Perappadan BS. Drug regulator warns about Meropenem, Disodium. *The Hindu.* 2024 March 12[Cited 2026 Jan 15]. Available from: https://www.thehindu.com/sci-tech/health/cdsco-issues-caution-against-manufacture-and-sale-of-unapproved-drugs/article67943220.ece