

COMMENTARY

DEG deaths: Why is India unable to stop them?

REMA NAGARAJAN

Abstract

The deaths of children in Chhindwara in Madhya Pradesh from cough syrup adulterated with diethylene glycol (DEG) have laid bare the gaps in drug regulation, from the manufacturing site down to the pharmacist. They have exposed, as hollow, the governments' and drug regulators' announcements of higher manufacturing standards for medicines, regular inspections of manufacturing units and stringent action against those found flouting regulations — after similar mass poisonings from DEG in cough syrup reported in 2020, 2022 and 2023. The Chhindwara tragedy has revealed a drug regulatory system that has not only failed repeatedly to make medicines safe, but also actively fights any public scrutiny of its functioning.

Keywords: cough syrup, DEG poisoning, drug regulation

The death toll in the latest mass poisoning from cough syrup has crossed 20 in Chhindwara, Madhya Pradesh (MP), as of October 17, even as many more children are in hospital fighting for their lives. However, the actual toll may never be known, as there does not seem to be any record of how many bottles of this cough syrup have been distributed and where.

The Chhindwara deaths sum up the abject failure of regulation in India — a poor health system that failed to pick up early signs of poisoning from contaminated cough syrup; a non-functioning adverse event reporting programme; drug regulation that does not stop repeated contamination that causes injuries and deaths, and an absence of any mechanism for recall of contaminated or toxic medicines.

The cough syrup that killed scores of children was contaminated with diethylene glycol (DEG), an industrial solvent used in brake fluids, antifreeze, resins and dyes among other things. Ingesting even a small amount of DEG can cause acute kidney failure resulting in permanent disability or death, especially among children.

DEG is an adulterant for pharmaceutical grade glycerin that is commonly used to thicken liquid medicines. DEG is colourless, odourless, sweet and viscous like glycerin — but costs much less. It finds its way into liquid medicines such as cough syrups intentionally or accidentally through the drug manufacturer's supply chain. Hence, regulations mandate that manufacturers test glycerin for potential contamination before using it in a medicine.

In the cough syrup that killed children in MP, the concentration of DEG was found to be 48%. The permissible limit is 0.1% [1].

Regulation and the US example

Almost 100 years after it became known that DEG is a deadly adulterant in medicines, hundreds, perhaps thousands, of children in low- and middle-income countries continue to die from DEG poisoning. In the last 40 years, DEG deaths have been reported from Nigeria, Bangladesh, Argentina, China, Haiti, Panama, The Gambia, Cameroon, and Uzbekistan. Over 230 child deaths in Bangladesh in 1992, 219 in Panama in 2006 and 178 in Indonesia were some of the largest reported mass poisoning incidents due to DEG [2]. Most of these were due to medicines made in India.

The first recorded DEG poisoning in India was in Chennai in 1972, when 15 children died from contaminated medicine. Since then, at least 14 people died in 1986 in Mumbai, 11 in 1988 in Bihar, 33 in 1998 in Gurgaon and 12 in J&K and 1 in Himachal in 2020 [3]. The regulator's response each time has largely consisted of a flurry of inspections and a short-term ban, with no substantial action to ensure the safety of medicines.

In contrast, after an outbreak of DEG poisoning in the United States (US) in 1937, in which 107 persons, many of them children, were killed, the Federal Food, Drug and Cosmetic Act was passed, requiring manufacturers to demonstrate the safety of their products before marketing them [4]. The US has not recorded DEG-related deaths since then, demonstrating how effective implementation of drug regulation can work.

Lobbying against compliance?

Drug makers are responsible for ensuring that the drugs they make are safe for consumption, and for this they must follow the Good Manufacturing Practices (GMP) contained in Schedule M under the Drugs and Cosmetics Rules of 1945. They are required to test every batch of raw material and the final product, as well as maintain records of where they have sourced the materials from, and the tests done. When using glycerin as a raw material, they are required to verify its purity and ensure that it has not been adulterated with DEG. The Central Drugs Standard Control Organisation (CDSCO) urges — but does not specifically require — thorough background checks, quality assessments and audits essential to ensure that suppliers meet regulatory standards and uphold ethical practices [5], a tall ask in the current leaky and weak regulatory environment. Additionally, the ideal regulatory system ought to be able to trace every product from the pharmacist, the stockist and so on all the way back to the manufacturer and to the suppliers

of each ingredient in the drug. The same should be possible in reverse. Such tracking requires meticulous documentation all through the chain of suppliers and distributors.

On October 5, 2018, the Indian government published a draft of the Revised Schedule M to update and align India's GMP for pharmaceutical products with international standards. The final notification for the Revised Schedule M was issued in December 2023. Large manufacturers were given six months to comply, and small and medium manufacturers were given a year.

Following small and medium manufacturers' representations to the government, this deadline has been extended to December 2025 — though they have already had plenty of time to meet compliance standards, as the draft has been available in the public domain since 2018 [6].

Inspection gaps

The central drug regulator claims to have organised extensive nationwide training programmes for drug manufacturers and other stakeholders to ensure effective understanding and implementation of the revised guidelines [7]. These efforts have apparently been underway for some years. Yet, inspections conducted after the latest DEG mass poisoning revealed that at many manufacturing sites, drugs continue to be made in horrifying conditions.

The Tamil Nadu regulator's detailed report after inspection of Sreesan Pharmaceuticals, the manufacturer of the cough syrup that killed children in Madhya Pradesh, recorded 364 violations. These included unhygienic conditions, absence of quality checks before releasing batches, different products being handled in the same room, purified water not being checked before use in manufacturing, and absence of registers for recording distribution details [8]. In Madhya Pradesh, the drug regulator inspected ARC Pharmaceuticals near Indore and found 216 violations, which included using water contaminated with fungi for manufacturing cough syrup, storing the syrup in unhygienic plastic containers, and straining it through a dirty cloth into bottles. The company had no record of testing for DEG [9].

The problem is not necessarily one of staff shortages. There are 14 senior drug inspectors and 148 drug inspectors in Tamil Nadu, for the approximately 400 drug manufacturing units registered in the state [10]. If each senior drug inspector physically checked just three units in a month, they would finish checking all 400 units once a year as stipulated. When was Sreesan Pharma last physically inspected before the recent mass poisoning? There are 79 drug inspectors for almost 270 drug manufacturing units in MP, according to the government's 2021 data [11]. That is less than four units to be inspected by each inspector in a year. Did any inspector visit ARC Pharmaceuticals even once a year? CDSCO has its own staff in each state to carry out joint inspections with the state regulatory staff. It lists 14 inspectors in South zone, Chennai

and three in Indore sub-zone. How many inspections of manufacturing units in these zones has CDSCO initiated?

In fact, do we have any information on the regulators' actions against pharma units? Is information regarding the last physical inspection of any of the units found to be grossly deficient available in the public domain? Do we know which inspector/s did the last inspection and when? Will the drug inspector/s be charged with negligence and arrested for allowing a manufacturing site like Sreesan Pharmaceuticals to function for more than a decade, endangering people's lives?

Kneejerk responses to public outcry

In March 2023, India "permanently" cancelled the licence of Marion Biotech that was linked to child deaths in Uzbekistan [12]. Four months later, in August, the company was allowed to resume production of all products not containing propylene glycol as there was "no known case of a lack of quality in other medicines manufactured by the firm". The case against the company and its owners for selling adulterated cough syrup that killed children drags on [13].

Similarly, the premises of Reimann Labs in Madhya Pradesh that manufactured the cough syrup that killed children in Cameroon were sealed and its licence suspended in August 2023, as the state licensing authority confirmed several violations. Its cough syrups were found to contain a 26% concentration of DEG.

Within a year, Riemann Labs' owner reopened operations under the same license number at a different location nearby. The state drug regulators took no action against the company, claiming they were still trying to trace the supply chain. The regulator filed a case against Reimann only on October 8, 2025, possibly because of the recent focus of DEG-related deaths in MP [14].

Clearly, such cancellations seem to be knee jerk responses to the public outcry following child deaths, and easy to roll back. Two years after the child deaths linked to cough syrups in The Gambia, Cameroon and Uzbekistan, when the CDSCO conducted inspections of pharma units, samples collected from over 100 pharma units failed quality tests. The inspection report stated that many companies failed to test for DEG and ethylene glycol (another toxic solvent for which testing is required), and the samples contained toxins like DEG and ethylene glycol [15]. This year, too, the inspections [16,17], triggered by the recent DEG-related deaths uncovered pharma units in Tamil Nadu, Madhya Pradesh and Gujarat making cough syrups contaminated with DEG. What use are detailed safety protocols in GMP when drug makers are allowed to continue to flout them with impunity?

Profiteering from irrational drugs

Cough and cold preparations are among the most frequently prescribed medicines by physicians. A study on

cough and cold preparation in India between 2004 and 2007 found that there were over 1,300 products in the market. Over 90% of them were fixed dose combinations (FDCs) with three or four constituents. The study found that most were irrational combinations and had no documented benefit in the treatment of common cold or cough. Yet hundreds of pharma units churn out irrational FDC cough and cold syrups, despite advisories from paediatric bodies and health authorities exhorting rational use of these syrups, particularly among children, as most coughs are self-limiting and do not require pharmacological treatment [18].

Cough syrups are relatively simple to manufacture and can be highly profitable, making them very attractive for pharma companies. It is estimated that one third of the Rs 22,000 crore cough syrup market in India is cornered by small and medium enterprises, many of which, as inspections show, do not follow even basic good manufacturing practices.

Yet, the steep commissions these companies offer convince doctors and unqualified practitioners to prescribe, and chemists to push, little-known brands. For instance, a brand manufactured in a unit in Mohali was sold to the retailer at Rs 19 per bottle while its maximum retail price was Rs 135, on which a 15% discount was offered to the consumer. That works out to about Rs 95 as commission on every bottle sold. Another brand sold for Rs 18 per bottle to retailers had an MRP of Rs 160 [19]. Such huge margins help those pushing the drug overlook advisories on not prescribing/recommending cough syrups to children under age four. Incidentally, none of the cough syrups being sold in MP had the warning recommended by CDSCO on the label or packaging: "FDC should not be used in children below 4 years of age" [20].

Using loopholes in the law

In Madhya Pradesh, authorities found that the cough syrup was being sold from a pharmacy owned by a family member of the doctor prescribing it. The pharmacy operated from the ground floor of the doctor's residence [21]. Doctors' associations have protested the arrest of this doctor pointing out that while it is illegal for a doctor to own or operate a pharmacy, no such restriction extends to his/ her family — a loophole widely exploited. They are mum on why the doctor flouted the CDSCO advisory.

No adverse event reporting

DEG-related deaths have been in the news on a regular basis for over four years. The symptoms of DEG poisoning — nausea, vomiting, abdominal pain, and diarrhoea and decreased to no urine output and eventually acute kidney injury — have been reported widely. Yet when an unusual number of children/persons are brought to the hospital with these symptoms and/or with unexplained acute renal failure, doctors don't seem to consider DEG toxicity as a possibility, and report this. Though the first DEG-related child death in Madhya Pradesh happened in early September, the health system failed to react. Though the central government had

been informed, it took the authorities two weeks to test the cough syrup and put out a public warning [22]. Had they reacted promptly, as expected, perhaps several lives could have been saved. There seems to be no system in place to trigger an alert when there is a clustering of cases with similar symptoms.

A more responsive healthcare system may have ensured prompt action including public warnings and recall of the product from the market. However, in India, recall is left to manufacturers. Drug regulators do not step in to ensure that it is done effectively.

No recall of toxic drugs

Poor documentation, billing practices and traceability plague not only pharma companies but the medicine distribution networks as well. So, recalls are not effective. The fallout of this was evident in the September 2020 death of a child in Himachal from a cough syrup made by the same company whose cough syrup (with a similar brand name and identical batch numbers) had killed 12 children in J&K between December 2019 and January 2020.

In what is a familiar sequence of events, state drug regulatory authorities rushed to give clean chits to drug companies. However, that was stymied as the drugs involved in the J&K and the Himachal cases were tested in the laboratory of the premier Post Graduate Institute of Medical Research, Chandigarh, and found to be contaminated [23].

Had regulators initiated an effective recall of all cough syrup from the same company after the J&K deaths, the cough syrup would not have remained in the market and killed the child in Himachal. We only know of the children who reached Chandigarh. It is anyone's guess how many more deaths or kidney failures never got reported as a DEG-related death or poisoning.

When will public health become a priority?

The Indian government's default mode every time a child is poisoned by DEG has been one of vehement and public denial followed by management of headlines by announcing "stringent action", inspections, temporary shutting down of manufacturing units and a few arrests. Once public attention shifts, it is back to business as usual with no consequences for those who violated the regulations and caused the deaths.

In the MP deaths, the union health ministry was quick to rule out adulteration. It was forced to change its tune when the Tamil Nadu regulator went public confirming high levels of DEG contamination in the cough syrup samples, following up with a detailed inspection report of the manufacturing site [24].

After a number of DEG-related deaths in several countries linked to Indian companies, the government announced in

June 2023 that cough syrups for export would be tested at government-approved laboratories. But there was no such directive for those supplying to the domestic market.

The existence of dubious companies carrying out drug manufacturing like a backyard operation without maintaining basic hygiene, forget good manufacturing practices, and the thriving of repeat offenders and blacklisted companies is a reflection of the state of drug regulation. It is clearly not just a case of an understaffed and underfunded regulatory system, so much as a case of a deliberately opaque regulatory system that actively fights transparency and public scrutiny [25]. Without consistent public pressure the government is unlikely to seek greater accountability and transparency from the drug regulatory system or legislate to make it unviable for drug manufacturers who game safety regulations. Or else, once the media glare shifts, it is back to business as usual till the next mass DEG poisoning.

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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 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