

## REVIEW ARTICLE ON BANNED DRUGS IN INDIA

**Prashant Shivaji Narode, Mangesh Nandkishor Dhone, Pankaj Pratap Sanap, Sumit Haribhau Tambe, Abhishek Annasaheb Pande.**

Gajanan Maharaj College Of Pharmacy, Chh. Sambhajinagar.

Prashantnarode18@gmail.com

**PROF. Tooba Khan**(M.pharm)(Department OF Pharmaceutics)Gajanan Maharaj College Of Pharmacy, Chh. Sambhajinagar.

**Dr. Kavita Kulkarni**(Phd.Mpharm), Department Of Quality Assurance, Gajanan Maharaj College Of Pharmacy, Chh. Sambhajinagar.

### Abstract

*The term "drug" comes from the Greek word "droughe" meaning a herb. Drugs can have a variety of therapeutic effects, but they can also lead to side effects, known as adverse drug reactions. These reactions can be either short-term or long-term. Occasionally, even drugs that have been properly approved and tested in clinical trials can cause serious problems when given to large groups of people.*

*The veterinary drug diclofenac has caused three species of Gyps vultures in South Asia to nearly go extinct. In response, the Indian government banned its use in May 2006. To assess how well this ban worked, we surveyed over 250 veterinary and general pharmacies across 11 Indian states between November 2007 and June 2010. During this time, we bought twelve different types of non-steroidal anti-inflammatory drugs (NSAIDs) from 176 pharmacies.*

*In September, the Indian government banned the manufacture, sale, and distribution of 328 Fixed-Dose Combination (FDC) drugs after a lengthy legal struggle with manufacturers. This decision was based on a report from an expert panel appointed by the Supreme Court, which found that these drugs lacked any therapeutic value and could actually pose health risks to patients.*

**Key Words:** Drug, adverse reaction, banned drug, non-steroidal anti-inflammatory drugs, NSAIDs, vultures.

### Introduction:

A pharmaceutical agent or medicine is a chemical used to diagnose, treat, prevent, or cure diseases and promote health. Different countries have their own lists of banned drugs, and it's concerning that some

medications banned elsewhere due to harmful effects are still available in India. Many of these drugs can be bought over the counter, and people might take them without realizing the risks involved. If the negative effects of a drug outweigh its benefits, or if it turns out to be ineffective, the country might ban it, or the company that makes the drug might choose to withdraw it voluntarily.

Fixed-dose combinations (FDCs) are medications that combine two or more active ingredients into a single pill or dosage form. These combinations typically involve drugs from different categories that work well together. The main benefits of FDCs include making it easier for patients to stick to their treatment, reducing the number of pills they need to take, minimizing complications, and lowering costs. However, it's important to note that the safety profile of the individual drugs can change when they are mixed in one formulation.

The Drug Controller General of India is the main authority responsible for approving or banning medications in the country. Some dangerous drugs that are banned in many parts of the world are still available in India. These banned medicines can be harmful and are often used to enhance performance rather than for their intended health benefits. Their production or use is either

completely prohibited or strictly regulated and usually requires a prescription.

A drug is basically any substance that changes how the body functions when it's absorbed. There isn't a single definition because it varies across laws, regulations, and everyday conversation. Legally, a drug is defined as a chemical used to treat, cure, prevent, or diagnose diseases, or to improve physical or mental well-being.

Before a drug hits the market, it goes through extensive testing to ensure it works effectively and is safe to use. However, some side effects might not show up until the drug is used by a larger population. To catch these potential issues, there's a process called pharmacovigilance, which involves ongoing monitoring of the drug's effects after it's been released.

Drugs go through strict testing before they're sold to the public. First, they're tested on animals, then in clinical trials with people. Both their effectiveness and safety are evaluated. However, some side effects only show up after the drug is used widely in the general population. To catch these issues, a system called pharmacovigilance monitors the drugs after they hit the market.

If serious side effects arise, or if the risks of a drug outweigh its benefits, a country might ban it, or the drug company may choose to withdraw it voluntarily. Sometimes, certain side effects occur only when a drug is taken with others, leading to a ban on specific combinations rather than the individual drugs. In India, several single drugs and fixed-dose combinations have been banned from being made, sold, or distributed.

#### **Reasons for banned drugs in India:**

1. **Cost of Drugs:** The price of medications is a huge factor for many people in India. Many are looking for affordable options, even if those drugs are banned. With a significant portion of the population living below the poverty line, the demand for low-cost drugs is strong.
2. **Lack of Awareness:** There's a low level of awareness about the potential side effects and interactions of medications. Many people don't know about the dangers associated with certain drugs, especially those not available in India, leading to their widespread use.
3. **Mindset About Quick Fixes:** Many individuals have developed a habit of using certain drugs for quick relief from minor issues like coughs and colds, regardless of whether those drugs are safe or legal.
4. **Drug Regulations:** The enforcement of drug laws in India is quite lax, which allows banned substances to remain easily accessible, even if they're officially listed as prohibited.
5. **Manufacturers' Interests:** Pharmaceutical companies are often more focused on meeting their financial targets than on patient safety. They produce drugs at low costs to maximize profits, sometimes at the expense of health.
6. **Physicians' Practices:** Some doctors may continue to prescribe banned drugs, even if they know about the risks. This raises concerns about patient safety.
7. **Underreporting of Adverse Effects:** Adverse drug reactions (ADRs) are often not reported in India. Most healthcare professionals don't document these effects, which

- contributes to the ongoing use of banned drugs without proper oversight.
8. These issues highlight a complex situation that requires better education, stricter regulations, and more accountability in the healthcare system to protect patients.
  9. Adverse drug reactions: (ADRs) are harmful and unintended responses to medications that happen even when the drugs are used at normal doses for treating or preventing diseases or for altering body functions. Pharmacovigilance is the field that focuses on detecting, assessing, understanding, and preventing these negative effects, both in the short and long term.
  10. In India, the Drug Controller General is the top authority responsible for approving or banning drugs. If a drug is found to have dangerous side effects, the government will issue a ban, instructing all manufacturers and wholesalers to stop selling it.
  11. In India, the process for banning drugs that are already prohibited in developed countries is often lengthy and complicated. This delay allows manufacturers to continue producing these banned drugs, driven largely by the commercial interests of pharmaceutical companies, corruption, and a lack of transparency and accountability within regulatory bodies.
  12. Regulatory agencies often lack the power to enforce bans effectively. Meanwhile, many drugs are sold at low prices, making them accessible to people living below the poverty line. As a result, many patients may not be aware that certain drugs, like Nimesulide, Rofecoxib, and Phenylpropanolamine, are banned, or they may not know about the potential side effects.
  13. Self-prescription is common, with patients believing these drugs provide quick relief for common ailments such as colds, coughs, and headaches. This practice has led to an increase in allergic reactions and serious health issues. Public awareness campaigns are needed to educate people about the risks of self-prescribing and the status of banned drugs.
  14. Additionally, the high cost and unavailability of safe alternatives can force patients to turn to these banned drugs. Healthcare providers often lack the knowledge and training to keep up with drug regulations, and in some regions, like Ludhiana, there's insufficient communication about the status of banned drugs, often relying on newspapers for updates.
  15. A recent example involves phenformin, which remains on the market despite being banned since 2003. This illustrates a significant gap in communication between the Drug Controller General of India (DCGI) and state drug controllers.
  16. Furthermore, there aren't enough drug inspectors to monitor all pharmacies and wholesalers, leading to gaps in compliance. The Ministry of Health and Family Welfare provides a list of banned drugs under the Drugs and Cosmetics Act of 1940, and while several formulations have been banned, there's a pressing need for healthcare professionals to stay updated on these lists.

17. Ultimately, ensuring patient safety during drug treatment is crucial. Healthcare professionals, including pharmacists and marketers, must familiarize themselves with the list of banned drugs to make informed decisions about treatment and marketing strategies.

#### **List of drugs banned in India:**

- **Single drug preparations**

1. Amidopyrine
2. Phenacetin
3. Nialamide
4. Methaqualone
5. Methapyriline (and its salts)
6. Practolol
7. Penicillin skin/eye ointment
8. 8  
Tetracycline/Oxytetracycline/Demeclocycline liquid oral preparations
9. Chloral hydrate
10. Dover's powder and Dover's powder tablets I.P.
11. Chloroform exceeding 0.5% w/w or v/v in pharmaceutical preparations.
12. Mepacrine HCl (Quinacrine and its salts) in any dosage form for use for female sterilization or contraception
13. Fenfluramine
14. Dexfenfluramine
15. Terfenadine
16. Astemizole
17. Phenformin
18. Rofecoxib
19. Valdecoxib
20. Rosiglitazone
21. Nimesulide formulations in children below the age of 12 years
22. Cisapride
23. Rimonabant
24. Phenyl Propanolamine

25. Human Placenta Extract in topical application for wound healing and injection for pelvic inflammatory diseases.

26. . Sibutramine
27. R-Sibutramine
28. Gatifloxacin
29. Tegaserod.

- **Fixed dose combination with any other drug**

1. Corticosteroids with any other drug for internal use.
2. Chloramphenicol with any other drug for internal use.
3. Sodium bromide/chloral hydrates with other drugs.
4. Ergot with any drug except preparations containing caffeine, analgesics, ergotamine, antihistamines for treatment of migraine.
5. Anabolic steroids with other drugs.
6. Metoclopramide with other drugs
7. Pectin and/or kaolin with any drug which is systematically absorbed from G.I. tract, except for combination of pectin and/or kaolin with drugs not systematically absorbed.
8. Hydroxyquinolines with any other drug except in preparations for external use.
9. Oxyphenbutazone or phenylbutazone with any other drug.
10. Dextropropoxyphene with any other drug except antispasmodics and/or NSAIDs.

- **Fixed dose drug combinations**

1. Penicillin with Sulfonamide
2. Tetracyclines with Vitamin C
3. Vitamins with Tranquillizers.
4. Atropine and Analgesic-antipyretics.

5. Yohimbine and Strychnine with Testosterone and Vitamins
  6. Iron with Strychnine, Arsenic and Yohimbin
  7. More than one Antihistamine in the same preparation.
  8. Laxative and/or antispasmodic drugs in enzyme preparations
  9. Centrally acting Antitussive and/or Antihistamine in preparations for cough associated with
  10. Pyrazinamide with other antitubercular drugs, except that which provide the following daily doses.
- **List of Drugs Prohibited for Manufacture and Sale through Gazette Notifications under Section 26a of Drugs & Cosmetics act 1940 by the Ministry of Health and Family Welfare.**

Drugs Prohibited from the date of Notification

    - Amidopyrine
    - Fixed dose combinations of vitamins with anti-inflammatory agents and tranquilizers.
    - Fixed dose combinations of Atropine in Analgesics and Antipyretics.
    - Fixed dose combinations of Strychnine and Caffeine in tonics.
    - Fixed dose combinations of Yohimbine and Strychnine with Testosterone and Vitamins.
    - Fixed dose combinations of Iron with Strychnine, Arsenic and Yohimbine.
    - Fixed dose combinations of Sodium Bromide/chloral hydrate with other drugs.
    - Phenacetin
  - Fixed dose combinations of antihistaminic with anti diarrhoeals
  - Fixed dose combinations of Penicillin with Sulphonamides.
  - Fixed dose combinations of Vitamins with Analgesics.
  - Fixed dose combinations of any other Tetracycline with Vitamin C.
  - Fixed dose combinations of Hydroxyquinoline group of drugs with any other drug except for preparations meant for external use.
  - Fixed dose combinations of Corticosteroids with any other drug for internal use.
  - Fixed dose combinations of Chloramphenicol with any other drug for internal use
  - Fixed dose combinations of crude Ergot preparations except those containing Ergotamine, Caffeine, analgesics, antihistamines for the treatment of migraine, headaches.
  - Fixed dose combinations of Vitamins with Anti TB drugs except combination of Isoniazid with Pyridoxine Hydrochloride (Vitamin B6).

I No.	Generic name	Brand name	Indication	Brand name
1	Oxyphenbutazone	Sioril, Phenabid Suganril	Inflammatory pain	Bone marrow depression
2	Metamizole	Analgin	Inflammatory pain Constipation Hyperacidity	Arrythmias
3	Cisapride	Cisa Syspride	Acidity Constipation	Irregular heartbeat
4	Nimesulide	Nise, Nimulid	Pain killer	Liver failure
5	Phenylpropanolamine	D cold, Vicks action 500	Cold, Cough	Hemorrhagic stroke
6	Quinodochlor	Enteroquinol	Antiamoebicidal	Subacute myeloid optic neuropathy
7	Cerivastatin	Baycol	Cholesterol lowering	Rabdomyolysis (damage to muscles)
8	Droperidol	Droperol	Antidepressant	Irregular heart beat
9	Furazolidone	Furoxone Lomofen	Antidiarrhoeal	Cancer
10	Nitrofurazone	Furacin, Emufurazone	Anitbacterial cream	Cancer
11	Thioridazine	Mellaril	Antipshchotic drug	Arrythmia Eye damage
12	Pergolide	Permax	Parkinson's disease	Heart valves damage
13	Piperazine citrate	Avizine, Anypar	Anthelmentic	Nerve damage
14	Tegaserod	Tegon, Tegaspa	Irritable bowel syndrome Constipation	Heart attack Stroke
15	Phenacetin	Achrocidin Codempiral	Analgesic Antipyretic	Renal diseases
16	Phenolphthalein	Prulet Phenolax	Stimulant purgative	Cancer
17	Gatifloxacin	Gatiflo	Antibiotic	Hyperglycemia
18	Rosiglitazone	Avandia	Type 2 diabetes	Heart attack
19	Rofecoxib and Valedecoxib	Vioxx, Bextra	Painkiller	Heart attack, Stroke
20	Phenformin	Bidiabile	Antidiabetic	Lactic acidosis
21	Terfenadine	Hismanal Seldane	Anti-allergic	ventricular tachycardia
22	Sibutramine	Reductil Sibutrex	Weight loss	Heart related diseases

### Drugs banned in abroad and still available in India:

#### Methods

Between November 2007 and June 2010, veterinary pharmacies in 11 states were surveyed. The pharmacies were located in urban areas and were likely legally registered and managed by qualified pharmacists. Researchers visited over 250 pharmacies, gathering information on the types of non-steroidal anti-inflammatory drugs (NSAIDs) available for purchase. They successfully collected data from 176 pharmacies that stocked at least one NSAID.

The survey involved field biologists, veterinarians, and trained volunteers—primarily Indian nationals from the same states as the pharmacies. They approached the pharmacies to buy NSAIDs for treating livestock without pretending to be farmers. In Uttarakhand, a local livestock owner did request treatment for a sick animal, specifically mentioning previous use of diclofenac.

During the visits, standard forms were completed, recording details such as the date, pharmacy name, location, and, if

possible, samples of the NSAIDs purchased. Information was also collected on the types of NSAIDs, their brands, forms (injectable or oral), manufacturing dates, and prices.

In the southern states of Kerala, Tamil Nadu, and Karnataka, as well as in Jharkhand, shopkeepers were asked about their awareness of the ban on diclofenac and its link to the decline of vulture populations, as well as whether human-use diclofenac was available for veterinary use.

ata collection varied by state, so some adjacent states were combined for meaningful comparisons. The areas were categorized into four regions: south (26 pharmacies in Andhra Pradesh, Karnataka, Kerala, and Tamil Nadu), central (31 in Madhya Pradesh and Maharashtra), west (57 in Rajasthan and Gujarat), and north (27 from Uttarakhand and Jammu & Kashmir). Jharkhand's data were presented separately. Most pharmacies stocked only one brand of any specific NSAID, so comparisons across the country and regions focused on the types of NSAIDs available rather than the number of brands per pharmacy.

#### REASON FOR BAN:

Generic name	Use	Reason for ban	Brand names(s)
1. Analgin	Pain-killer	Bone-marrow depression	Novalgin, Baralgin

2. Cisapride	Acidity , constipation	Irregular heart beat	Ciza, Syspride
3. Droperidol	Anti-depressant	Irregular heart beat	Droperol
4. Furazolidone	Anti-diarrhoeal	Cancer	Furoxone, Lomofen*
5. Nimesulide	Pain-killer, fever	Liver failure	Nise, Nimulid
6. Nitrofurazone	Anti-bacterial cream	Cancer	Furacin , Emfurazone
7. Phenolphthalein	Laxative	Cancer	Jetomisol-P
8. Phenylpropylamine	Cold & cough	Stroke	D'Cold , Vicks Action 500
9. Oxyphenbutazone	NSAID	Bone marrow depression	Sioril
10. Piperazine	Anti-worms	Nerve damage	Piperazine, Helmazan*

11. Quiniodochlor	Anti-diarrhoeal	Damage to sight	Enteroguinol
Denotes it is a combination product Analgin, Furazolidone and Nitrofurazone are banned for use even in animals in the United States. Analgin is banned even in Nepal, Vietnam and Nigeria (Reference: MIMS INDIA, September, 2005)			

**Cause and Effects :**

**1. Analgin - (Novalgin, Baralgin)**

Use: Pain relief.

Side Effect: Can cause bone marrow depression, meaning it reduces the body's ability to produce blood cells, leading to weakness or infections.

**2. Cisapride- (Ciza, Syspride)**

Use: Treats acid reflux and constipation by speeding up stomach emptying.

Side Effect: May cause irregular heartbeats, which can be dangerous.

**3. Droperidol- (Droperol)**

Use: Helps with nausea and used as a sedative. Sometimes classified as an antipsychotic, but here mentioned as an antidepressant.

Side Effect: Can cause irregular heart

**4. Furazolidone- (Furoxone, Lomofen)**

Use: Treats diarrhea and certain bacterial/parasite infections.

Side Effect: Long-term use might increase the risk of cancer.

**5. Nimesulide - (Nise, Nimulid)**

Use: Relieves pain and reduces fever.

Side Effect: Can lead to liver failure if used excessively or in sensitive individuals.

#### 6. Phenolphthalein - (Jetomisol-P)

Use: A laxative that helps relieve constipation.

Side Effect: Long-term use might increase the risk of cancer.

#### 7. Oxyphenbutazone - (Sioril)

Use: An NSAID (Non-steroidal anti-inflammatory drug) for pain relief.

Side Effect: Can cause bone marrow depression, reducing blood cell production, which can lead to serious health issues.



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Phenylpropanolamine  
Rimonabant

(PPA) I

List of some common drugs that are banned in India



**Sibutramine**

**Phenylpropanolamine (PPA)**

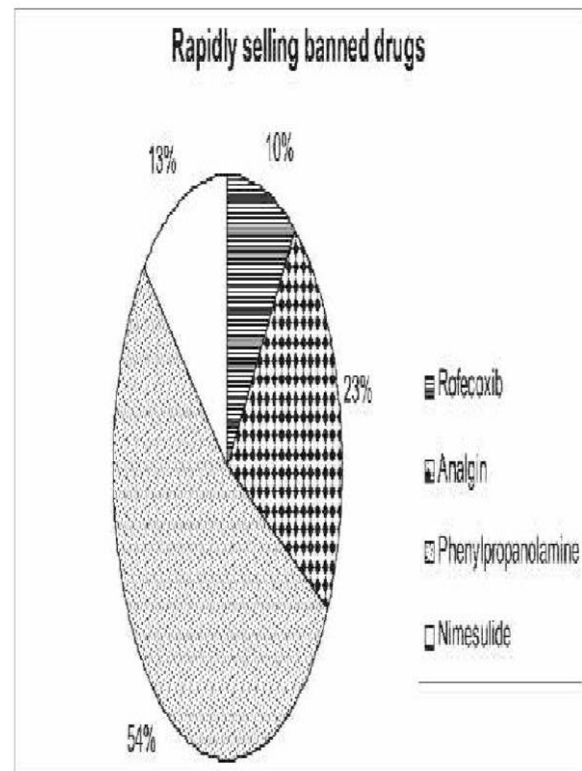
**Rapidly selling banded drugs in India**

The issue of banned drugs being sold rapidly in India is a complex and concerning problem. It often involves a mix of illegal trafficking, inadequate law enforcement, and public health challenges.

1. **Illegal Market:** Despite strict laws, a black market exists where banned substances are sold, often through online platforms or street dealers.
2. **Health Risks:** The use of these drugs can lead to serious health issues, including addiction and overdose, impacting individuals and communities.
3. **Law Enforcement:** Efforts to combat drug trafficking can be hampered by corruption, lack of resources, and the vastness of the country.
4. **Public Awareness:** Education about the dangers of drug use is essential

to reduce demand and prevent addiction.

5. **Government Initiatives:** The Indian government has been working on various strategies to combat drug abuse, including rehabilitation programs and stricter regulations.



**Drugs recall by FDA:**

1. **Rofecoxib (Vioxx):** Available from 1999 to 2004, this NSAID for arthritis was linked to over 28,000 heart attacks in the U.S. Merck withdrew it after concerns about its safety.
2. **Valdecoxib (Bextra):** This NSAID was recalled due to serious risks, including skin reactions and increased chances of heart attack

and stroke. The FDA determined it didn't offer significant advantages over existing pain relievers.

3. **Troglitazone (Rezulin):** Marketed from 1997 to 2000, this diabetes medication caused 90 liver failures and at least 63 deaths, leading to numerous lawsuits against its manufacturer.
4. **Efalizumab (Raptiva):** Approved in 2003 for psoriasis, this drug was pulled from the market in 2009 due to the risk of a fatal brain infection.
5. **Pemoline (Cylert):** Available from 1975 to 2010 for ADHD, this stimulant had a boxed warning added in 1999 due to potential liver damage before it was eventually recalled.
6. **Bromfenac (Duract):** This pain reliever was on the market in 1997 and caused multiple serious liver injuries and deaths due to improper dosing beyond its recommended 10-day limit.
7. **Terfenadine (Seldane):** This antihistamine, available from 1985 to 1998, was recalled after it was found to cause serious heart problems when taken with certain other medications.
8. **Aminopyrines:** These medications can cause agranulocytosis and aplastic anemia, leading to bans in many developed countries, although they are still available in some regions.
9. **Phenacetin:** Introduced in 1887, this painkiller was discontinued in

the U.S. in 1983 due to its association with kidney damage and potential cancer risks.

10. **Nialamide:** An antidepressant withdrawn from the market due to risks of liver toxicity.
11. **Methaqualone:** Classified as a Schedule I narcotic in the 1980s due to its high potential for addiction and lack of medical necessity in the U.S.

These cases highlight the importance of monitoring drug safety and the potential consequences of medications that are later found to pose serious health risks.

#### **Conclusion:**

Safety of patient is prime factor in the treatment of diseases and drug therapy contributes a major part of it. Consumption of the banned drugs by patients may pose severe complications and even be lethal also. So, strict enforcement of laws over the drugs must be passed by the government. Public awareness programme should be conducted educating drug usage and its adverse effects. If the prescriber stops prescribing these harmful drugs then chemist will automatically stop selling and no manufacturer will manufacture these drugs. To stop selling of banned drugs we need cumulative work of prescriber, pharmacist, manufacturer, researcher and the people.

Ensuring patient safety is crucial in disease treatment, and responsible drug therapy plays a significant role in this. The use of banned drugs can lead to serious complications or even be fatal. Therefore, it's essential for governments to enforce strict laws regarding these drugs.

Raising public awareness about the dangers of improper drug use is also vital. If healthcare providers stop prescribing harmful medications, pharmacies will naturally follow suit and manufacturers will cease production. To effectively eliminate the sale of banned drugs, we need a collective effort from doctors, pharmacists, manufacturers, researchers, and the community. Working together, we can protect patients and promote safer healthcare practices.

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