Available online on 15.12.2023 at http://ajprd.com

Asian Journal of Pharmaceutical Research and Development

Open Access to Pharmaceutical and Medical Research

Open Access

Review Article

A Review on Banned Drugs

Ghodake Vaishnavi S*, Hangargekar Sachin, Yelkote Priyanka D, Gurav Mohini A, Siddiqui Ayesha N, Honrao Madhav, Rohini Sante, Phulari Madhuri.

Shivlingeshwar College of Pharmacy, Almala Dist. Latur -413520 Maharashtra (MH), India

A B S T R A C T

India has become a hub for the availability and usage of banned or harmful medicines such as Nimesulide, D'cold, Novalgin, Lomofen, and Rofecoxib, among others. The decision to ban a drug is based on the risk versus benefit ratio evaluated through post-marketing surveillance and the Adverse Drug Reaction Reporting System. Pharmaceutical negligence among doctors can lead to hazardous effects on the general health of a patient. It is important for the government to spread information on drugsideeffects. The prescribing of drugs is an essential practice for medical professionals. In promoting a healthy lifestyle, the prevention of diseases is important, but equally important is treatment of such diseases with safe drugs. Every drug has some side effects, but with the correct dosage, it can be avoided. Banned drugs have more adverse/side effects. Drugs that are found unsafe in post-marketing surveillance are banned by regulatory authorities. The Drug Controller General of India (DCGI) is the highest authority in India to approve or ban a drug. Despite this, banned drugs are still available in developing countries such as India due to a lack of law enforcement, physician awareness, and drug control authorities failing to inform hospitals of the status of medicine. India is a major hub for banned drugs.

Keywords: -Nimesulide, Novalgin, Adverse Drug Reaction, Banned Drugs, Post Marketing Surveillance.

A R T I C L E I N F O: Received 30 June 2023; Review Complete 10 Sept. 2023; Accepted 08 Dec. 2023; Available online 15 Dec. 2023

Cite this article as:

Ghodake Vaishnavi S, Sachin H, Yelkote Priyanka D, Gurav Mohini A., Siddique Ayesha N., Honrao Madhav, Rohini Sante, Madhuri P, A Review on Banned Drugs, Asian Journal of Pharmaceutical Research and Development. 2023; 11(6):31-35.
DOI: http://dx.doi.org/10.22270/ajprd.v11i6.1331

*Address for Correspondence:
Ghodake Vaishnavi Shivaji, Department of Pharmaceutics, Shivlingeshwar College of Pharmacy, Almala, Dist. Latur-Maharashtra (MH), India

INTRODUCTION:

A drug is any chemical or synthetic substance that is used to cure, prevent, or diagnose diseases or to enhance physical or mental well-being [2]. However, banned drugs are those that are prohibited from being taken due to their potential to artificially improve performance and cause various adverse effects that outweigh their therapeutic benefits [1].

Before drugs are introduced to the market, they undergo strict testing. They are first tested on animals and then on human beings during clinical trials to evaluate their efficacy and safety profiles. Despite this, some drugs may have adverse effects that only become apparent after they are used in the general population. Moreover, India continues to sell many counterfeit drugs that have been banned, withdrawn, or marketed under restrictions in other countries.

In the past decade, Nonsteroidal Anti-Inflammatory Drugs (28%), antidiabetics (14.28%), anti-obesity (14.28%), antihistamines (14.28%), gastroprokinetic drugs (7.14%), breast cancer and infertility drugs (7.14%), irritable bowel syndrome and constipation drugs (7.14%), and antibiotics (7.14%) were the most frequently withdrawn drug categories. Most drug withdrawals from the market were due to safety issues involving cardiovascular events (57.14%) and liver damage (14.28%).

Regulation and Guidelines: -

In India, the Drug Technical Advisory Board (DTAB) is responsible for banning drugs with harmful side effects. A committee examines the potential risks of drugs and reports its findings to the DTAB [4].The Drug Controller General of India then notifies all state drug authorities and manufacturers about the ban. at IPA, we understand the

challenges that pharma professionals face when seeking regulatory information for compliance purposes, both within India and in foreign markets. After the ban is announced, the DCGI informs all state drug authorities, pharmacist associations, and manufacturers, and authorities carry out inspections to ensure compliance. If pharmacists continue to stock banned drugs, they risk having their licenses revoked under the Drugs and Cosmetics Act [4]. Additionally, the Central Drugs Standard Control Organization, a government organization in India, has developed guidelines for the list of drugs banned in the European Union and the USA.

Table 1: Government Drops 19 Drugs from National List of Essential Medicine (NLEM) 2022 Over Cancer Causing Fears: -

Sr. No.	Name of the Drugs
1.	Alteplase
2.	Atenolol
3.	Bleaching powder
4.	Capreomycin
5.	Cetrimide
6.	Chlorpheniramine
7.	Diloxanide furoate
8.	Dimercaprol
9.	Erythromycin
10.	Ethinylestradiol
11.	Ethinylestradiol (A)+Norethistradiol(B)
12.	Ganciclovir
13.	Kanamycin
14.	Lamivubine(A)+Nevirapine(B)+Stavudine(C)
15.	Leflunomide
16.	Methyldopa
17.	Nicotinamide
18.	Pegylated interfernon alfa 2a, Pegylated interfernon alfa 2b
19.	Pentamidine

When a new drug is introduced to the market, its primary goal is to improve patient's quality of life. However, every drug comes with its own set of adverse effects [2].Therefore, before a drug is released to the public, it undergoes rigorous testing to ensure its efficacy and safety profile. This process is known as pharmacovigilance. If harmful side effects are detected after a drug is released, the government may issue a ban order, and all manufacturers and wholesalers must stop stocking the medicine. In India, the "Drug Controller General of India" is the highest authority that can approve or ban a drug [15]. When deciding whether to use, cautiously use, or ban a drug, factors such as unexpected adverse effects, excess toxicity, availability of safer alternatives, harmful interactions, irrational use, and failure of risk management options are taken into consideration [16].

If doctors stop prescribing drugs that are harmful to patients' health, chemists will automatically stop selling them since there will be no demand for them. Consequently, manufacturers will not produce them. By doing so, much of the problem can be solved. Manufacturers have every reason to sell their products if there is a demand for them.

India has become a destination for banned drugs to be dumped. The problem is that very few people are aware of these drugs and end up consuming them unknowingly, causing damage to their health. This issue is severe and we must act fast to spread the warning message to both the offenders and innocent people. These drugs can cause serious organ damage, such as kidney and liver damage. Although each country has its own list of banned drugs, it is alarming that some drugs that are banned in other countries due to proven adverse effects are still available in the Indian market. The majority of analgesics, anti-diarrheal, and cough preparations that are banned in other countries are easily accessible in India as over-the-counter drugs[5].This is mainly due to lack of awareness among physicians and patients, poverty, self-medication, high cost, and communication gap between DCGI and state drug controller[2].The Health Ministry of India has finalized that if any drug is banned by two or more countries and is still being marketed in India, it will be banned in India as well[1].

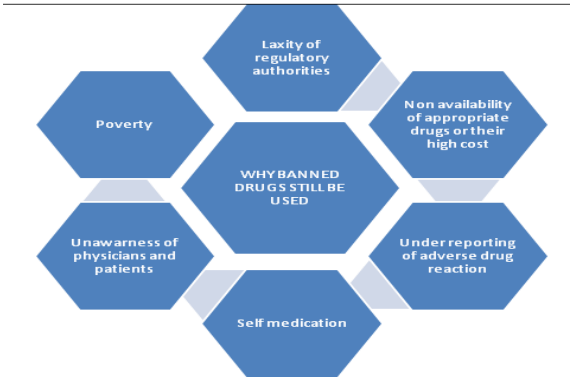

Figure 1: Why Banned Drugs Still Be Used?

Most of the Drugs Banned in Other Countries but Available in India: -

It is crucial to be aware of the possible side effects of medications used to treat various medical conditions. Below are examples of some drugs and their potential adverse effects:

- **Oxyphenbutazone:** This Non-Steroidal Anti-Inflammatory Drug (NSAID) is used to alleviate pain, osteoarthritis, and fever. However, individuals with stomach problems, high blood pressure, fluid retention, abdominal discomfort, heartburn, abdominal cramps, nausea, vomiting, and diarrhea, headache, dizziness, drowsiness, blood in urine, and kidney failure should use it with caution.
- **Metamizole (Dipyrone):** This drug is used to reduce pain and fever, but it can harm the bone marrow and cause digestive disorders.
- **Cisapride:** This prokinetic agent is used to treat Gastroesophageal Reflux Disease (GERD), but it has been found to cause irregular heart rhythms. Its effectiveness in treating constipation in children is also unclear.
- **-Nimesulide:** This Non-Steroidal Anti-Inflammatory Drug is used to treat painful inflammatory conditions, back pain, and dysmenorrhea.
- **Cerivastatin:** This drug blocks enzymes in the liver that produce cholesterol, thus preventing the risk of heart attack and stroke. However, it has several side effects, such as diarrhea, nasal congestion, constipation, headache, heartburn, muscle damage, and difficulty breathing.
- **Droperidol:** This antidopaminergic is used as an antiemetic and antipsychotic, and for neuroleptanalgesic anesthesia and sedation intensive-care treatment. However, it can cause sedation, hypotension, and prolongation, which can lead to extrapyramidal side effects such as dystonic reactions.
- **Phenylpropanolamine:** This prokinetic agent is used to treat GERD, but it can cause heart stroke and heart attack.
- **Quiniodochlor:** This antibacterial agent is used to treat dermatophytosis, mycosis barbae, seborrheic dermatitis, infected eczema, furunculosis, and pityriasisi veriscolor. It can cause nausea, transient loose and green stools, itching, and goiter.
- **Furazolidone:** This nitrofuran antibacterial is used to treat diarrhea and enteritis caused by bacterial or protozoan infections, cholera, bacteremic salmonellosis, and Helicobacter pylori infections. However, it has many side effects, and like other nitrofurans, can cause systemic toxicity such as tremors, convulsions, peripheral neuritis, gastrointestinal disturbance, and depression of spermatogenesis.
- **Nitrofurazone:** This drug is bactericidal for most pathogens that commonly cause surface skin infections. It is indicated as an adjunctive therapy for second and third-degree burns. The adverse effects that have been selected based on their potential clinical significance are itching, rash, and swelling.

The following drugs have been associated with adverse effects that could be life-threatening or significantly impact the quality of life: **-**

- **Thioridazine:** This antipsychotic medication is prescribed to treat schizophrenia. However, it may cause a dangerous heart rhythm disorder and uncontrollable muscle movements in the face, arms, legs, eyes, lips, or tongue.
- **Pergolide:** This drug is typically used to manage Parkinson's disease. However, it can damage the cardiovascular system and cause other adverse effects.
- **Piperazine:** Initially used as a solvent for uric acid and later as an anthelmintic for worm infections, this medication may cause blurring of vision, clumsiness, a crawling or tingling sensation on the skin, fever, twisting or irregular movements of the face, legs, or arms, joint pains, itching, or skin rash.
- **Phenolphthalein**: This astringent is commonly used as a laxative. However, it may increase the risk of heart stroke and attack, agranulocytosis, leucopenia, thrombocytopenia, proteinuria, and interstitial nephritis. Sensitive patients may also experience rashes, urticaria, quincke's edema, asthmatic attacks, and, very rarely, anaphylactic shock., urticaria, quincke's edema, asthmatic attacks, and, very rarely, anaphylactic shockare possible.

Misuse of Drugs: -

Misuse and abuse of drugs pose significant health problems. Drugs that have harmful effects are regulated according to classification systems that are supposed to reflect the risks and harm associated with each drug [11]. Illegal drugs, along with alcohol, tobacco, cocaine, and opiate drugs, create substantial social costs for society. Cocaine and opiate drugs were first criminalized in 1914, followed by marijuana in 1937, in the US. The criminalization of these drugs has resulted in the modern "war on drugs," which is characterized by strict enforcement of drug laws and policing efforts aimed at shutting down the drug trade [12].

However, prohibiting drug use does more harm than good to both drug users and society as a whole. Legalizing drugs would simultaneously reduce crime rates and improve law

enforcement. It's hard to imagine any other single measure that would do so much to promote law and order.

Irrational Use of Drugs: -

The misuse of certain drugs like Nimesulide, a non-steroidal anti-inflammatory drug, is a growing concern in India due to the potential risks it poses such as hepatotoxicity, cholestasis, pruritis, colon cancer, coagulopathy, and seizures (especially in children due to prolonged use to treat fever and pain), and in smokers over a period of time. Nimesulide is still used in India, despite being banned in the USA, Finland, Spain, Bangladesh, Portugal, Singapore, and Israel[7]. The production and promotion of certain banned and counterfeit drugs is also affecting the healthcare sector across the country. Nimesulide is one of the most commonly used medicines in India to cure pain and fever, but it has been banned in many countries due to serious side effects [8].

Phenylpropanolamine, another drug used in cough syrups, has been restricted in many countries due to reports of causing cardiac problems [9].

These drugs are used as analgesics, antipyretics, cough and cold remedies, and anti-diarrheals, but recent research has shown that long-term use can have detrimental effects on human health such as liver damage, irregular heartbeats, depression, blood pressure fluctuations, and damage to sight [10].

Awareness about Banned Drugs: -

Drugs have become an integral part of medical practice [6]. many of them are banned by governments due to harmful adverse effects. In developing countries like India, banned drugs are still available due to lack of law enforcement, physician awareness, and failure of drug control authorities to inform all hospitals. Commonly used drugs like Nimesulide, Furazolidone, Phenylpropanolamine, and other over-the-counter preparations are banned by the USFDA because of their side effects on the kidney, liver, and nerve. Unfortunately, analgesics, antidiarrheals, and cough preparations that are banned in other countries are blindly used in India as over-the-counter drugs because of unawareness, lack of law enforcement, and corruption. (As shown in fig no.2)

To address this issue, drug information centers should be opened to provide updated and unbiased information to prescribers and patients [14]. Pharmacists should take an interest in public information campaigns and educate consumers [2]. To stop the use of banned drugs, stricter law enforcement and greater physician awareness are also required.

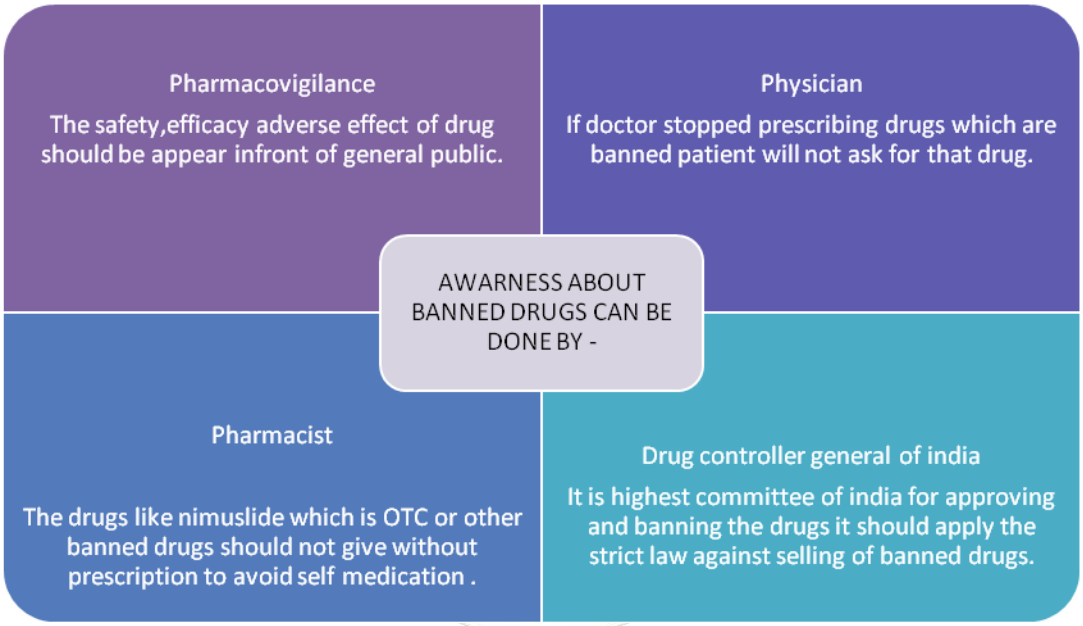

Figure 2: Awareness about Banned Drugs

Drug Control Strategy: -

The current strategy to control drug use involves various measures aimed at eliminating illegal drug usage. These measures include disrupting the drug market, community activism, and public information campaigns to raise awareness about the potential dangers of drug use, and law enforcement efforts against the different aspects of the supply chain through surveillance and undercover work [13].

CONCLUSION:

Although every country has its own list of prohibited drugs, it is concerning that some drugs, which are banned in other countries due to proven harmful effects, are still available in the Indian market. Some of these drugs are available over-the-counter, and people may take them without realizing the risks involved. This lack of awareness leads to the use of banned drugs as over-the-counter drugs and causes severe harm to people's health. Therefore, it is essential for the government to implement strict laws on manufacturers, wholesalers, and retailers. The government should be ordered to dispose of these cheap drugs properly, and awareness should be created among physicians, health professionals, and the general public about the Adverse Drug Reactions (ADR) of these drugs. This will play a crucial role in eliminating the banned drugs from the market.

ACKNOWLEDGEMENT: -

The Authors are thankful to Principal, Dharashive V. M. for providing the laboratory facility and his persistent creative encouragement and valuable guidance throughout the work. Also, I would like to thank my supervisor, for all his help, guidance and assistance throughout the work. It has been a great pleasure and wounderful learning experience to work under his supervision.

REFERENCES: -

1. https://ajpsonline.com/HTML Paper.aspx? Journal = Asian % 20 Journal % 20 of % 20 Research % 20in % 20 Pha rmaceutical % 20 Sciences; PID=2018-8-4-13
2. https://ajpsonline.com/HTML Paper.aspx? Journal = Asian % 20 Journal % 20 of % 20 Research % 20 in % 20 Pharmaceutical % 20 Sciences; PID=2018-8-4-13

3. https://www.researchgate.net/publication/291053675_Awareness_About_Banned_Drugs_A_Review
4. https://www.linkedin.com/pulse/awareness banned-drugs-india-gaurav–kumar-sharma
5. https://rjpdft.com/HTMLPaper.aspx ? Journal = Research % 20 Journal %20 of % 20 Pharmaceutical % 20 Dosage % 20 Forms % 20 and % 20Technology; PID=2019-11- 2-6
6. https://www.jcdr.net/article_fulltext.asp?id=349
7. Kiran Kabtta Somyanshi. Drugs banned abroad may still be use in some cases. The Economic Times.www.articles.economictimes.indiatimes.com/20130107/news/36192943_1_cdsco_drugs_standard_control_organization_side_effects.
8. Medic8. Nimesulide side effects online. 2010 Nov.5; Available From URL; http//www.ethow.com/facts_7312477_nimesulide_banned_html.
9. Tripathi KD. Essentials of medical pharmacology. New Delhi: Jaypee Brother Medical Publisher (P) Ltd; 1997.
10. Kernan WN, Viscoli CM, Brass LM. Phenylpropanolamine and the risk of hammorhagic stroke. N. Engl. J. Med. 2000; 343(25):1826-32.
11. Nutt D, King LA, Saulsbury W, Blakemore C. Development of a rational scale to assess the harm of drugs of potential misuse. Lancet. 2007; 369(9566):1047-53.
12. John J. Donohue lll, Rethinking Amerika's illegal drupolicy.www.ycsg.yale.edu/center/forms/ US-illegal drug policy-145-158.
13. http://enn.wikipedia.org/wiki/prohibition of drugs.
14. https://www.ijirt.org/Article?manuscript=152435
15. Gulhati CM. government commission ident useless, hazardous, irrational drugs. Monthly in of Medical Specialities, India Nov2005.
16. https://www.researchgate.net/publication/275653400_Awareness_about_Banned_Drugs_A_Matter _of_Concern.