

Awareness About Banned Drugs

DIVYA JIJABRAO PATIL

Abstract— India has become a dumping ground for banned drugs also the business for production of banned drugs is booming and many people don't know about these banned drugs and consume them causing a lot of damage to themselves. Doctors do not report side effects of any drug and the Drug Controller General of India (DCGI) is the sole authority to endorse the manufacture, sale and ban of a drug. Drug development process is a robust process that can make and assure a drug with least possible side effects for human consumption. After a series of quality control process only a drug can be released into market. But some adverse effects of drugs appear only after the drug is used in general population. If the adverse-affects are severe or the risks of using the drug outweigh the benefits, or if the drug is ineffective, the country may ban the drug or the Drug Company may itself voluntarily withdraw the drug. Some drugs may cause adverse effects only when combined with particular drugs. In such cases, only the fixed dose combination is banned and not the individual drugs. A number of single drugs as well as fixed dose combinations have been banned for manufacture, marketing and distribution in India. The present review is an attempt to provide some information about the individual drugs that are banned in India with their reason of banning

Indexed Terms- Banned Drugs, Indian Drugs, Pharmacovigilance, FDA.

I. INTRODUCTION

A drug is “a chemical or synthetic substance used in the, cure, prevention or diagnosis of disease or used to otherwise enhance physical (1). “PILL FOR EVERY ILL” is a saying which is being focused and pursued. It may not be possible to have a disease-free world but we can aspire for solutions to relieve misery and make patient's life more comfortable (8).

BANNED DRUG:

banned drugs are drugs that not allowed to intake because they could artificially improve their performance and shows various adverse effects more than therapeutic effects.

“Drug Controller general of India” is the highest authority in India to expand the approval of any drug or to ban a drug. Some of the dangerous drugs have

been globally discarded but are available in India. The most common are like NIMESULIDE, PHENYLPROPANOLAMINE, FURAZOLIDONE, etc. (1).

REASON FOR BANNING DRUG:

The main aim is to ensure good quality of life to patients but every drug comes with its own adverse effects. Before egrouse test passing in manufacturer's development then after a serious of quality control process only a drug can be released into the market. A drug may show toxicity only after it is introduced in the market and not at the time of clinical trials. These causes several adverse effects after drug introduced in to market called pharmacovigilance. If any harmful side effects are detected the government issue the ban order and all the manufacturer and wholesaler are asked not to stock the particular medicine (10)



PHARMACOVIGILANCE:

PHARMACOVIGILANCE is the Pharmacological technology referring to the detection, evaluation information and prevention of negative outcomes, particularly, long-time period and short-time period side-outcomes of medicines. “Drug Controller general of India” is the maximum authority in India to extend the approval of any drug or to prohibit a drug. If any is to have dangerous side-outcomes, the authorities trouble the ban order and all producer and wholesaler are asked now no longer to stock the specific medicine.

“If medical doctors forestall prescribing drugs that are dangerous to patients` health, chemists will robotically forestall promoting since there are no patients asking for Rashes, boom fee (CAGR) each year (6)

WHY INDIAN STILL SELLING BANNED DRUG:
Some drugs are still available in India because gap between Drug Controller General India and State Drug Controllers as well as unawareness of physicians and patients, poverty, self-medication, carelessness of regulatory authorities, non-availability of appropriate drugs, high cost, and communication. The irony is that very few people know about the banned drugs and

consume them unaware, causing a lot of damage of themselves. The issue is severe and we must not delay in spreading the warning message to the offenders and innocent people [10]. One fact the many banned drug available over the counter with changed formulation but same brand name. The drugs are available without prescription so the general population is ignorant about the serious side effects.

India has serious issues with use, availability and distribution of banned drugs (5).

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 with their present status as on 22.11.2021.

| S.No | Drug Name | Notification No. & Date |
|------|---|---|
| 1 | Amidopyrine. | GSR NO. 578(E) Dated 23.07.1983 |
| 2 | Fixed dose combinations of vitamins with anti-inflammatory agents and tranquilizers. | GSR NO. 578(E) Dated 23.07.1983 |
| 3 | Fixed dose combinations of Atropine in Analgesics and Antipyretics. | GSR NO. 578(E) Dated 23.07.1983 |
| 4 | Fixed dose combinations of Strychnine and Caffeine in tonics. | GSR NO. 578(E) Dated 23.07.1983 |
| 5 | Fixed dose combinations of Yohimbine and Strychnine with Testosterone and Vitamins. | GSR NO. 578(E) Dated 23.07.1983 |
| 6 | Fixed dose combinations of Iron with Strychnine, Arsenic and Yohimbine. | GSR NO.578(E) Dated 23.07.1983 |
| 7 | Fixed dose combinations of Sodium Bromide/chloral hydrate with other drugs. | GSR NO.578(E) Dated 23.07.1983 |
| 8 | Phenacetin | GSR NO. 578(E) Dated 23.07.1983 |
| 9 | Fixed dose combinations of antihistaminic with anti-diarrhoeal. | GSR NO.578(E) Dated 23.07.1983 |
| 10 | Fixed dose combinations of Penicillin with Sulphonamides. | GSR NO. 578(E) Dated 23.07.1983 |
| 11 | Fixed dose combinations of Vitamins with Analgesics. | GSR NO. 578(E) Dated 23.07.1983 |
| 12 | Fixed dose combinations of any other Tetracycline With Vitamin C. | GSR NO. 578(E) Dated 23.07.1983 |
| 13 | Fixed dose combinations of Hydroxyquinoline group of drugs with any other drug except for preparations meant for external use. | Substituted vide GSR NO. 793(E) Dated 13.12.1995 |
| 14 | Fixed dose combinations of Chloramphenicol with any other drug for internal use. | Substituted vide GSR NO. 1057(E)Dated 03.11.1988 |
| 15 | Fixed dose combinations of crude Ergot preparations except those containing Ergotamine, Caffeine, analgesics, antihistamines for the treatment of migraine, headache. | Substituted vide GSR NO. 304 (E)Dated 07.06.1991 |

REASONS FOR AVAILABILITY OF BANNED DRUGS IN INDIA:

1. Commercial pastimes of pharmaceutical organizations
2. Corruption
3. Lack of straightforwardness and responsibility
4. Regulatory our bodies want implementation control.
5. Due to the neediness line in India those medicines are effects showcased at low expenses
6. Many non-public experts and medical doctors are ignorant approximately the withdrawal
7. Non-Compliance with the aid of using the affected person with out all and sundry else`s enter recommending the medicines for primary ailments and scatters(8).
8. Because of self medicine, portions of hypersensitive and anaphylactic responses are occurring each every so often in India. This may be avoided with the aid of using open mindfulness applications with recognize to the status, utilize, and reactions of self solution.
9. Non-accessibility of becoming medicines and their magnificent expense. Prescribers absence of gaining knowledge of and experience
10. One of the functions in the back of the loose accessibility of pulled lower back medicines withinside the marketplace is that this correspondence hollow among the DCGI and nation drug controllers(6).

MOST OF THE DRUGS BANNED IN OTHER COUNTRIES BUT AVAILABLE IN INDIA

Oxyphenbutazon: Oxyphenbutazone, a metabolite of phenylbutazone, is an NSAID. It has been used for episcleritis, osteoarthritis, and rheumatoid arthritis etc. the severe adverse effects of oxyphenbutazone, which give rise to further complications include allergic reactions, abdominal pain, blurred vision.

Metamizole: Metamizole (Dipyrone) belongs to a group of drugs that eliminate pain and reduce fever. Metamizole can cause damage to the bone marrow (granulocytopenia, agranulocytosis, hemolytic anemia, aplastic anemia.), digestive disorders etc.

Cisapride: Cisapride is a "PROKINETIC AGENT" that used for treatment of gastroesophageal reflux disease (GERD). There is no evidence it is effective for this use in children. evidence for its use in

constipation is not clear. It has been found to cause cardiac arrhythmias (irregular heart rhythms)

Nimesulide: Nimesulide is a non-steroidal anti-inflammatory drug, used for painful inflammatory conditions, back pain, dysmenorrheal, postoperative.

Furazolidone: Furazolidone is a Nitrofurans Antibacterial. It is marketed under the brand name furoxone. furazolidon has been used in human and veterinary medicine. in humans it has used to treat diarrhea and enteritis caused by bacteria or protozoan infections. it has been used to treat cholera and bacteremic salmonellosis, and helicobacter pylori infections. it has many side effects, and as with other nitro furans generally, minimum inhibitory concentrations also produce systemic toxicity (tremors, convulsions, peripheral neuritis, gastrointestinal disturbance, depressions of spermatogenesis.

Nitrofurazone: Nitrofurazone is bactericidal for most pathogens that commonly cause surface skin infections. Topical nitrofurazone is indicated as an adjunctive therapy second and third degree burns. The adverse effects have been selected on the basis of their potential clinical significances are itching, rash and swelling

Thioridazine: Thioridazine is an antipsychotic medicine called a phenothiazine. It is used to treat schizophrenia. But it can cause a life-threatening heart rhythm pain, osteoarthritis and fever. Caution should be exercised in patients with history of stomach problem, high blood pressure, fluid retention, abdominal discomfort, heartburn, abdominal cramps, nausea, vomiting and diarrhea, headache, dizziness and drowsiness, blood in urine and kidney failure.

Phenylpropanolamine: Phenylpropanolamine is a "PROKINETIC AGENT" that used for treatment of gastroesophageal reflux disease (GERD). But heart stroke and heart attack can cause due to adverse effect of phenylpropanolamine.

Quiniodochlor: Quiniodochlor is a antibacterial agent, used for dermatophytosis, mycosis barbae, seborrheic dermatitis, infected eczema, furunculosis, and pityriasisi veriscolor. It caused to nausea, transient loose and green stools, itching and goiter.

Cerivastatin: Cericastatin prevents the risk of stroke and heart attack .it functions by blocking away the enzymes in the liver that is responsible in the production of cholesterol inside the body. There are several side effects associated by using

CERIVASTATIN, for example- diarrhea, nasal congestion, constipation, headache and heartburn, muscle damage, sexual problems, fever, difficulty in breathing etc.

Droperidol: Droperidol is an Antidopaminergic drug used as an antiemetic and antipsychotic. It also often used for neuroleptanalgesic anesthesia and sedation in intensive-care treatment. but it causes dysphoria, sedation, hypotension resulting from peripheral alpha adrenoceptor blockade, prolongation of qt interval which can lead to extra pyramidal side effects such as dystonic reaction disorder, uncontrollable muscle movements of your lips, tongue, eyes, face, arms or legs.

Pergolide: Pergolide is a drug normally used for the treatment of parkinson’s disease. But cardiovascular system can damaged as the adverse effect of pergolide.

Phenolphthalein: Phenolphthalein is a astringent normally used as a laxative. The several adverse effects of phenolphthalein are heart stroke and heart attack etc.

THE ANNUAL SALE OF BANNED DRUG :

In India [17] [18] The government has banned drug as many as 1,670 drug brands, estimated total annual sales of Rs 3,728 crore (Rs 37.28 billion), an analysis by IMS Health shows. the 344 fixed drug combinations which were banned by the government last week, triggering protests and legal action by pharma industry. The various Indian pharma companies manufactured banned drugs.

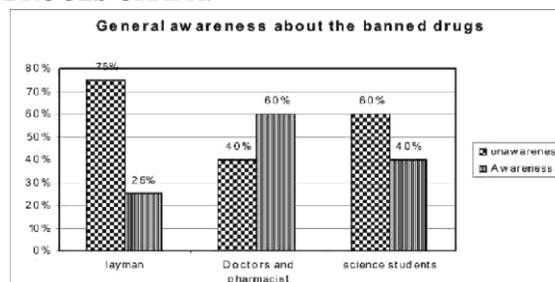
| company | Banned product | Annual sales |
|-------------------|--|----------------------------------|
| Pfizer | Corex and Corex-DX | Rs 423 crore (Rs 4.23 billion) |
| Macleods Pharma's | skin cream Panderm+ | Rs 228.2 crore (Rs 2.28 billion) |
| Abbott's | cough syrups Phensedyl, Tixylix and Tossex | Rs 290 crore (Rs 2.9 billion) |
| Lupin's | Gluconorm -PG | Rs 46.5 crore (Rs 465 million), |
| | Glimepiride+Pioglitazone+Metformin | Rs 525 crore |
| | Chlopheniramine Maleate+Codeine | Rs 700 crore (Rs 7 billion) |

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|-----------------|--|------------------------------|
| GlaxoSmithKline | Crocin Cold and Flu, Piriton-CS, Dilo-DX and Piriton | Rs 58 crore (Rs 580 million) |
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AWAENESS ABOUT BANNED DRUG:

Drugs become an integral part of medical practice. 8 Due to harmful adverse effects of the drugs many of them are banned by government. But banned drugs are still available and People consume them unaware, these long term use of such medicines can put negative impact on human health in various ways by damage liver, kidney or any organ.(3) In present scenario of increasing global burden of diseases, the prime concern of manufacturers and health care professionals is to ensure quality drugs with maximum therapeutic benefit and minimum side effects. Unexpected adverse effects, excess toxicity, availability of safer alternatives, harmful interactions, irrational use and failure of risk management options are the prime reasons which direct whether to use, cautiously use or ban a drug .(3)Where as in India, banning of a drug is a lengthy procedure leading to availability of banned drugs in market for a long time even after the drug is banned in other countries. Non seriousness towards health and lack of effective policies by government are the primary reasons for much delay in banning the drugs in India which leads to increase in disease burden and economic stress on Indian community .(2) . A drug is banned depending upon the benefit risk analysis and drugs with more risk are immediately banned by the regulatory authorities by knee jerk response so as to ensure the safety of population. Regarding safety of drugs being used, European countries seem more aware as compared to our country (4) .

GENERAL AWARENESS ABOUT THE BANNED DRUGS GRAPH:



CONCLUSION

In conclusion one can say that, though several drugs are banned or restricted for sale in developed countries, such as USA these banned drugs are still being sold in developing countries such as India. Therefore it becomes important for the government to implement laws, strict on manufacturers, wholesalers and retailers'. There should be creation of awareness amongst physicians, health professionals and general public about the ADR of these drugs. If all these steps are taken in a well defined and unified way the market for these banned drugs can be eliminated permanently and rapid

The drugs are chemical or synthetic substance which used for diagnosis, treatment, mitigation and prevention of a disease, disorder and otherwise enhance physical or mental well-being. Before egrouse test passing in manufacturing development then after a series of quality control process only a drug can be released into market. The importance manufacturers and their local regulatory agencies cannot be over emphasized information about banned drug, which importance of pharmacists, other health-care professionals, physicians and patients to continue to report serious suspected adverse drug reactions known.

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- [4] D. Sunitha1*, K. Hemalatha2 , M. Sudhakar1 1Malla Reddy College of Pharmacy (Osmania University), Maisammaguda, Hyderabad, Telangana. 2Acharya B. M. Reddy College of Pharmacy, Bangalore, Karnataka.
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- [6] Khedkar Shivaji Vitthal*1, Sonal Shinde*2, Wamane Vikas Bhausahab*3 *1Student At Pratibhatai Pawar College Of Pharmacy, Shirampur, India. *2,3Assistant Professor At Pratibhatai Pawar College Of Pharmacy, Shirampur, India.
- [7] Survase Rutuja Ramdas1 , Lad G. S2 , Shyamlila B. Bavage 3 , Nandkishor B. Bavage 4 1B. Pharmacy Final Year Student, Latur College of Pharmacy, Hasegaon,Tq.Ausa, Dist. Latur-413512, Maharashtra, India 2Department of Pharmacology, Latur College of Pharmacy, Hasegaon, Tq. AUSA, Dist. Latur-413512 Maharashtra, India 3Department of Pharmacognosy, Latur College of Pharmacy Hasegaon, Tq. AUSA, Dist. Latur-413512 Maharashtra, India 4Department of Pharmaceutical Chemistry Latur College of Pharmacy, Hasegaon, Tq.AUSA, Dist. Latur 413512 Maharashtra, India.