## A Review On Awareness About Banned Drugs

S.Manoj<sup>1</sup>, G.Mariyappan<sup>2</sup>

1,2 PALLAVAN PHARMACY COLLEGE

**Abstract-** The world is depend upon medicines to cure and prevent the diseases .The drugs may be single (or) combination drugs therapy. Many formulation are meant for prevention (or) treatment of ailment and diseases. Many serious problems occur in health care, there is always a "Knee-jerk", this response to impose a band and thus provide an immediate response to the issue. The developing countries like India also has many banned drugs are available .This is due to lack of law enforcement and physician awareness. The banned are dumped in because of for production of banned drugs is booming in India. The dangers drugs has been hardly discarded in other countries but still available in India.The common drugs are OXPHENBUTAZONE.NITROFUROFURONE.PHENOLPTH ALEIN are banned in US. The side effects on kidney, liver and nerves.India blindly using Analgesic,anti-diarrhoea and cough preparation,but in other countries are banned.The government, FDA and Pharmacist should make awareness and dangers effects on banned drugs.

*Keywords*- Banned Drugs, Indian Drugs, Reason for ban, Amidopyrine.

#### I. INTRODUCTION

A drug is a chemical (or) synthetic substance used as a remedy (or) avert from the disease. Before marketing the drugs undergo several stages of test for selling. The safety and effectiveness of the drugs are tested. Some adverse effects of the drugs are seemed only after the drug is dispensed to the patient. A drug is prescribed to a patient for its positive effect,but in some cases,it may cause dangers adverse effects to the patients. The adverse effect pose a risk greater then the safety provided by the drug. When the drugs are used in combination with other drugs, if it causes serious adverse effect. The combination of the drug is banned, but the individual drug is not banned. This kind of drugs are banned in several countries. The drug are banned by FDA (or) manufacture (or) production company .But in India in business motive some banned drugs are selling at low cast to the patients. Medical profession is getting defamed and crippled in India because of various facts like self medication,lack of knowledge among doctors.

#### **BANNED DRUGS**



The drugs that not allowed to intake (or) administrate for disease curing. The drugs shows various adverse effect more than therapeutic effects. "Drugs controller general of India" has the highest authority to approval of any drug (or) to ban a drug.

## AUTHORITY IN INDIA FOR APPROVAL/BAN THE DRUGS

- Central Drugs Standard Organization (CDSCO) under the Directorate General of Health Services
- Ministry of Health and Family Welfare
- National Regulatory Authority(NRA) of India

# WHY BANNED DRUG IN MANY COUNTRY STILL AVAILABLE IN INDIA

- Many of them are over the counter drugs (brands) are available with changed formulation but same brand name.
- They are available without prescription so the general population is ignorant about the serious side effects.
- The manufactures take the aid of pending court case and continue distribution until decision is made.
- The answer to such unethical distribution and availability of banned drug may lie in the insufficient data about ADR and its reporting.
- Many studies about pharmacovigilance and ADR reporting have shown very poor ADR reporting in the in India due to lack of knowledge and practice.
- Things get further complicated due to issue such as self medication, since it is not monitored by physical, and patients miss the important steps of getti9ng warned about then side effects of the drugs and the subsequent ADR reporting if any, is unavailable.

Page | 200 www.ijsart.com

- There is lack of awareness about the safety issues associated with medication or about the discontinued nature of medication and the consequences upon their consumption in India.
- The cost of drugs act as determinant of sale of banned drugs.

#### LIST OF DRUGS BANNED IN INDIA

GENERIC	NAME USE	REASON FOR BAN
Analgin	Pain-killer	Bone-marrow depression
Cisapride	Acidity, constipation	Irregular heart beat
Droperidol	Anti-depressant	Irregular heart beat
Furazolidone	Anti-diarrhoeal	Cancer
Nimesulide	Pain-killer, fever	Liver failure
Nitrofurazone	Antibacterial Cream	Cancer
Phenolphtalein	Laxative	Cancer
Phenylpropanamine	Cold and Cough	Stroke
Oxyphenbutazone	NSAID	Bone marrow depressions
Piperazine	Anti-worms	Nerve damage
Quiniodochlor	Anti-diamhoeal	Damage to sight
Practolol	Cardiac arrhythmias	Destruction of lacrimal glands
Metha qualone	Sedative, CNS	Renalinsufficiency, coma,
	depressant	death
Fenfluramine	Antiobesity	Cardio-toxicity

#### A. Single drug preparations (or combinations of)

- 1. Amidopyrine
- 2. Phenacetin
- 3. Nialamide
- 4. Methaqualone
- 5. Methapyriline (and its salts)
- 6. Practolol
- 7. Penicillin skin/eye ointment
- 8. Tetracycline/Oxytetracyline/Demeclocycline liquid oralpreparations.
- 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 formulatios in Children Below the age Of 12 years
- 22. Cisapride
- 23. Rimonabant
- 24. Phenyl Propanolamine

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

## B. fixed dose combination with any other drug

1. Corticosteroids with any other drug for internal use.

ISSN [ONLINE]: 2395-1052

- 2. Chloramphenicol with any other drug for internal use.
- 3. Sodium bromide/chloral hydrate with other drugs.
- 4. Ergot with any drug except preparations containing ergotamine, caffeine, analgesics, antihistamines for treatment of migraine.
- 5. Anabolic steroids with other drugs. Metoclopramide with other drugs (except with aspirin/paracetamol).
- 7.Hydroxyquinolines with any other drug except in preparations for external use.
- 8.Oxyphenbutazone or phenylbutazone with any other drug.
- 9.Dextropropoxyphene with any other drug except antispasmodics and/or NSAIDs.
- 10. Analgin (metamizol) with any other drug.

#### C. Fixed dose drug combinations of

- 1. Penicillins with Sulfonamides.
- 2. Tetracyclines with Vitamin C
- 3. Antitubercular drugs with Vitamins (except Isoniazid with Pyridoxine HCl).
- 4. Vitamins with Analgesics/Antiinflammatory drugs.
- 5. Vitamins with Tranquillisers.
- 6. Atropine and Analgesic-antipyretics.
- 7. Yohimbine and Strychnine with Testosterone and Vitamins.
- 8. Strychnine and Caffeine in tonics.
- 9. Iron with Strychnine, Arsenic and Yohimbine.
- 10. Antihistaminics with Antidiarrhoeals.
- 11. More than one Antihistamine in the same preparation.
- 10. Sedatives/Hypnotics/Anxiolytics with Analgesic-antipyretics.H2 receptor antagonists with Antacids (except those combinations approved byDrugs Controller, India).
- 11. Anthelmintics (except Piperazine) with a Cathartic/Purgative.
- 12. Salbutamol (or any other bronchodilator) with centrally acting Antitussive and/or an Antihistamine.
- 13. Centrally acting Antitussives with Antihistamines having atropine like activity in expectorants.
- 14. Centrally acting Antitussive and/or Antihistamine in preparations for cough associated with asthma.
- 15. Laxative and/or antispasmodic drugs in enzyme preparations.
- 16. Glycerophosphates and/or other phosphates and/or CNS stimulant in liquid oral tonics.

Page | 201 www.ijsart.com

18. Ethambutol with Isoniazid, except in the following daily doses: Isoniazid 200 mg + Ethambutol 600 mg or Isoniaizd 300 mg + Ethambutol 800 mg

19. Pyrazinamide with other antitubercular drugs, except that which provide the following daily doses. Rifampicin 450 to 600 mg Isoniazid 300 to 400 mg Pyrazinamide 1000 to 1500 mg

20. Essential oils with Alcohol having percentage higher than 20% proof (except preparations given in the I.P.).

#### DRUG USES AND SIDE EFFECTS

**Oxyphenbutazone:** An NSAID, oxyphenbutazone is a metabolite of phenylbutazone. It has been applied to conditions like rheumatoid arthritis, osteoarthritis, and episceleritis. Allergies, abdominal pain, and blurred vision are just a few of the serious side effects of oxyphenbutazone that can lead to additional complications.

**Metamizole**: Dipyrone, also known as metamizole, is a medication that lowers fever and relieves pain.Digestive issues, bone marrow damage, hemolytic anemia, aplastic anemia, and other conditions can all be brought on by metamizole.

**Cerivastanin:** This drug lowers the chance of having a heart attack or stroke. It works by preventing the liver enzymes that are involved in the body's synthesis of cholesterol from doing their jobs. The use of CERIVASTATIN can cause a number of side effects, such as nausea, vomiting, diarrhoea, nasal congestion, constipation, headache, heartburn, muscle damage, erectile dysfunction, fever, and difficulty breathing.

Droperidol is an antidopaminergic medication that is used as an antiemetic and an antipsychotic. It is frequently used in intensive care treatments for sedation and neuroleptanalgesic anaesthesia. However, it results in drowsiness, hypotension via peripheral alpha adrenoceptor blockage, dysphoria, lengthening of the qt interval, and extra pyramidal side effects like dystonic response.

**Cisaprid**: Cisaprid is a "AGENT PROKINETIC" that is used to treat gastroesophageal reflux disease (GERD). There is no proof that it works for kids in this situation. There is unclear proof that it can relieve constipation. There is evidence that it causes cardiac arrhythmias (irregular heart rhythms)

**Nimesulide**: Nimesulide is a non-steroidal anti-inflammatory medication that is used to treat severe inflammatory disorders, back pain, dysmenorrhea, and post-operative pain.

ISSN [ONLINE]: 2395-1052

Furazolidone. It is offered under the furoxone brand name. The drug furazolidon has been applied to both human and animal health. It has been used to treat enteritis and diarrhoea in humans brought on by bacterial or protozoan diseases. Cholera, bacteremic salmonellosis, and helicobacter pylori infections have all been treated with it. It has a lot of negative side effects, and like other nitro furans generally, it can cause systemic toxicity at low inhibitory doses, which can lead to tremors, convulsions, peripheral neuritis, gastrointestinal disturbances, and spermatogenesis depressions.

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

**Quiniodochlor**: Quiniodochlor is an antibacterial agent used to treat pityriasis veriscolor, seborrheic dermatitis, furunculosis, and dermatophytosis. It resulted in goitre, itching, temporary loose and green faeces, and nausea.

**Phenylpropanolamine**: For the treatment of gastroesophageal reflux disease, phenylpropanolamine is a "PROKINETIC AGENT" (GERD). However, the adverse effects of phenylpropanolamine can end in heart attacks and strokes.

#### RECENTIY BANNED DRUGS

1. Amidopyrine

Use:Relieve several and persistent fever and pain.

Side effects: Nausea, epigastric pain, difficulty in hearing, liver damage.

Reason for ban:Most frequent blood dyscrasia,aplasic anaemia.

- 3. Fixed dose combinations of Atropine and Analgesic and Antipyretics.
- 4. Fixed dose combination of Vitamins with anti-inflammatory agents agent and tranquilizers
- 5. Fixed dose combination of strychnine and caffeine in tonics

#### RECALLING OF DRUGS

Page | 202 www.ijsart.com

The drug recall is the most potent way to protect the public from a defective or possible harmful product.

A recall is the voluntary action taken by a company at any time to remove a defective drug product from the market.

Drugs may be recall for an assortment of reasons including safety,miss labelling ,contamination and deviations in strength or potency.

Recalls may be conducted as a voluntary action by the manufacturer or supplier, by request from the FDA.

#### PHARMACOVIGILANCE IN INDIA, THE NEED

Pharmacovigilance in India was started in 1986 with a formal adverse drug reaction (ADR) monitoring system,under supervision of the drug controller of India.India joined the world health organization (WHO) programme for international drug monitoring in 1998, But was not successful. In 2005 the national programme of pharmacovigilance was launched. Then it was remarked as pharmacovigilance programme of India (PvPI) works for the safety of Indian people. Above 250 of adverse drug monitoring centre all over the India to improve patient safety and they also detected the prescribing, dispensing and administration errors, It also monitoring of generic drugs, bio-similar and diseases specific ADR of anti diabetic cardiovascular and anti-psychotic drugs and creating awareness. National co-ordination centre (NCC) also taken several plan for patient safety by surveillance and collaboration with national health program. For every five years the NCC programs a awareness among health care professional about reporting ADR . the NCC/PvPi collaboration with NSCB medical college in Jabalpur, created a mobile application for health care centre. The technology is developed to upgrade easy and instant reporting of ADR. On may 22,2015 this technique was launched by secretary health, MoHFW and government of India. On a global India is being prominent for clinical trial, drug discovery, and research development. The ADR reporting rate in India is below 1% compared to world rate of 5%.

### PROCESS OF BANNEDING

On India, the Drug Technical Advisory Board (DTAB) has the last say in whether to impose a ban. The harmful effects of the medications are investigated by an executive committee, and informs the DTAB of the findings. If a medication is discovered to the Government imposes the prohibition on products that have harmful side effects order, and all producers and retailers are prompted to not to keep the specific medication on hand. The DCGI reports all state drug

enforcement agencies, organizations of pharmacists, and producers of the medicine about the prohibition. Authorities are instructed to carry out inspections. The Drug and Cosmetics Act allows for the revocation of a pharmacist's licence if they are found to be stocking illegal medications.

The results are reported to the drugs technical advisory board

The government issues the ban order

DCGI notifies all state drug authorities

Authorities are instructed to carry out inspection

#### II. CONCLUSION

It is concerning that several pharmaceuticals that are prohibited in other nations due to their known adverse affects are still offered on the Indian market, despite the fact that each country has its own list of prohibited substances. Some of these medications are available on prescription, and individuals may use them without understanding the risks. Patients may decide whether to use the medicine by consulting a warning about it. Please ensure that customers only purchase medications that have been prescribed by a physician. Additionally, that came from a well-known drugstore. Because they are illegal, many individuals who do not know about them use them, harming themselves severely. Some experts say that illegal recreational drug use is generally risky for illegal drugs that are not diverted prescription restricted medicines; these problems include addiction, infection, and other adverse effects due to the unpredictable and unmonitored dosage and purity of the narcotics. The list of pharmaceuticals that the European Union and the United States have banned is strictly regulated by the Central Drugs Standard Control Organization, which is managed by the Indian government

### REFERENCES

- [1] Thawani .V, Sontakke. S, Gherpure .K, Pimpalkhute. Nimesulide the current controversy. Indian J. Pharmacol 2003; 35:121-2.
- [2] Panacea patient's nimesulide composition. Express Pharma, 2006; 21:129.

Page | 203 www.ijsart.com

- [3] Thawani V, Sharma S, Gharpure K. Pharmacovigilance: Is it possible if bannable medicines are available over the counter? Indian J Pharmacol 2005;37:191
- [4] Kulkarni SK, Jain NK. Coxibs: The new super aspirins or unsafe pain killers? Indian J Pharmacol 2005;37:86-9
- [5] Nandave MD, Ojha SK, Arya DS. Should selective Cox-2 inhibitors be used more? Indian J Pharm Sci 2006; 68:281-5.
- [6] Oricha BS, Muhammad BY. Dipyrone (Novalgin, Metamizole): Banned and Unbanned: The dilemma of commonly prescribed and over the counter analgesic. Annals of African Medicine 2003; 2(2):101-2.
- [7] Bapna JS, Dandiya PC. Analgin: 'Its Present Status and 'Possible Hazards. Ind. J. Pharmacol 1977; 9(3):233-5.
- [8] Study raises doubt on painkillers safety. Express Pharma 2006; 2(3):159.
- [9] Rahman SZ, Khan RA. Is nimesulide safe in a cardiovascular-compromised patient? Indian J. Pharmacol 2004; 36(4):252-3.
- [10] Khan S. Nimesulide and adverse drug reactions: Time for a database. J Postgrad Med 2008; 54:242.
- [11] Kumar S. Drug linked to child death is still available in India. BMJ 2003; 326:70.
- [12] Saha, K. Use of nimesulide in Indian children must be stopped. BMJ.2003; 326:713.
- [13] Khan AY, Ghilzai NM. Counterfeit and substandard quality of drugs: The need for an effective and stringent regulatory control in India and other developing countries. Indian J Pharmacol. 2007; 39:206-7
- [14] Karnan WN, Viscoli CM, Brass LM et.al. Phenyl propanolamine and risk of hemorrhagic stroke. N. Engl. J. Med 2000; 343:1826-32.
- [15] SoRelle R. FDA warns of stroke risk associated with phenylpropanolamine, cold remedies and drugs removed from store shelves. Circulation 2000; 102:E9041-3
- [16] After ban in India, docs warn diabetics of rosiglitazone use. Available from: http://www.indianexpress.com/news/after-ban-in-india-docs-warndiabetics-of-r/694755/[Last accessed on 2012 Oct 31].
- [17] The Times of India. Ban on Tegaserod, Gatifloxacine due to sideeffects. New Delhi. 2011, Available from: http://www.articles. timesofindia.indiatimes.com/2011-03-19/india/29146073\_1\_dipblood-sugar-levels-gatifloxacine-tegaserod. [Last accessed on 2012 Jun 29].
- [18] India today. Government bans nimesulide banned over adverse effects on liver. New Delhi. Available from: http://www.indiatoday.intoday. in/story/government-bans-nimesulide/1/129859.html [Last accessed on 2012 Sep 5].
- [19] Rahman SZ, Khan RA. Is nimesulide safe in a cardiovascularCompromised patient? Indian J Pharmacol 2004;36:252-3.

- [20] Khan RA, Rahman SZ. A case report on Nimesulide and its relation with angina. J Pharmacovigilance Drug Saf 2004;1:19-21.
- [21] Slimming drug Sibutramine banned in India. Available from: http:// www.indianexpress.com/news/slimming-drug-sibutramine-banned-in India/710526 [Last accessed on 2012 Oct 5].
- [22] Use of pain-killer Rofecoxib banned. Available from: http://www. hindu.com/2004/10/13/stories/2004101306241200.htm [Last accessed on 2012 Jun 28].
- [23] U.S. Food and Drug Administration, Bextra (valdecoxib) Apr 2005. Available from;http://www.fda.gov/Safety/MedWatch/SafetyInform ation/ SafetyAlertsforHumanMedicalProducts/ucm150752.htm [Last accessed on 2012 Oct 31].
- [24] Dance with shadows. India bans valdecoxib. Available from: http:// www.dancewithshadows.com/hara/india-ban-valdecoxib.asp [Last accessed on 2012 Oct 31].
- [25] Finally, expert panel bans fertility drug Letrozole. Available from: http://www.articles.timesofindia.indiatimes.com/2011-10-18/india/30296687\_1\_ letrozole-breast-cancer-post-menopausal-women [Last accessed on 2012 Oct 31].
- [26] Government may ban antiobesity drug Rimonabant, Available from: http://www.businessstandard.com/india/news/govt-may-ban-anti-obesitydrugrimonabant/343972/[Last accessed on 2012 Oc
- [27] Drugs Banned in other Countries But Available in India.

  Available from:

  http://www.medindia.net/patients/patientinfo/drugsbannedin-other-countries-but-available-in-india.htm [Last accessed on 2012 Oct 31].
- [28] Pharmacovigilance in UK.Availablefrom:http://www.liv.ac.uk/pharmacovigilance/pages/pharmuk.htm. [Last accessed on 2012 Oct 31].
- [29] United States FDA. FDA issues final risk minimization guidance. Available from: http://www.fda.gov/bbs/topics/news/2005. [Last accessed on 2012 Oct
- [30] FDA. Premarketing risk assessment guidance. Available from: http:// www.fda.gov/cder/guidance [Last accessed on 2012 Oct 31].
- [31] FDA. Development and use of risk minimization action plans. Available from: http://www.fda.gov/cder/guidance [Last accessed on 2012 Oct 31].
- [32] Pharmacovigilance Programme of India for assuring drug safety. Available from: http://www.cdsco.nic.in/pharmacovigilance.htm. [Last accessed on 2012 Oct 29]

Page | 204 www.ijsart.com

- [33] Banning all drug promotion is the best option pending major reforms. J. Bioethical Inquiry 2005; 2(2):75-81.
- [34] Yadav S. Status of adverse drug reaction monitoring and pharmacovigilance in selected countries. Indian J. Pharmacol 2008; 40(1):S4-S9.
- [35] Gautam CS, Aditya S. Irrational drug combinations: need to sensitize under graduate. Indian J Pharmacol 2006; 38(3):169-70.
- [36] Prakash S. Pharmacovigilance in India. Indian J Pharmacol 2007; 39:123 37. Chetley A. Problem drugs. London: Zed Books, 1995. 38. Mudur G. India admits to unapproved drug formulations in market. BMJ 2003; 326:1286.

Page | 205 www.ijsart.com