BANNED DRUGS

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ABSTRACT: Drug prescribing is the most vital workout of medical professionals. For healthy lifestyle ,not only the prevention of disease is important but equally important is the treatment of such diseases with safe drugs. A substance , such a drug , etc., that is Forbidden by law or other authority. Protecting the health of the athlete has become part of the fundamental rationale of the World Anti-Doping code which seeks to protect the health of the athletes. When serious problem occurs in health care there is always a "Knee-Jerk response by many to impose a ban and for that reason offer a right of way and definitive reaction to the issue. Banned tablets are nevertheless to be had in growing international locations like India because of loss of regulation enforcement and doctor awareness. The pharmacist ought to keep public data campaigns and train consumers, and for this reason play a critical function on putting off the marketplace for banned drugs. DC has been drawing attention from the pharmaceutical industries because of the government's ban on 328 irrational FDCs in September 2018.

KEY WORDS: Banned drugs, Pharmacovigilance, Drug recall, Drug withdrawal, Regulations, and guidelines.

INTRODUCTION:

Banned drugs are the ones which are not allowed to be administered because they cause various adverse effects more than the therapeutic effects. Generally, drug is a chemical or synthetic substance used for diagnosis, treatment, mitigation, and prevention of disease and used to enhance physical and mental wellbeing. The irony is that very few people know about the banned drugs and consume them unaware which leads to several side effects to them. These may lead to organ damage like kidney, liver damage etc. Through each country has its own list of Banned drugs [1]. The numbers of single drugs as well as fixed dose combinations drugs are banned in other countries but they have manufacturing, manufacturing, marketing, and distribution in India [2]. In present scenario of increasing global burden of diseases the prime concern of manufactures and health care professionals to ensure quality drugs with maximum therapeutic benefit and minimum side effect. Unexpected adverse effects, excess toxicity, availability of safer alternatives, harmful Interactions, irrational use and failure of risk management options are the primary reasons which direct whether to use, cautiously use or banned a drug. A drug is banned depending upon benefit risk analysis and drugs with more risk are immediately banned by the regulatory authorities by knee jerk response to ensure the safety of population.

Regarding safety of drugs being used, European countries seem more aware as compared to our country. Over the counter availability of banned drugs sufficient adverse drug reactions data about these drugs have not been reported. The adverse effect of drugs is detected by regular monitoring after the drug released pharmacovigilance[3]. Protecting the health of the athlete has become part of the fundamental rationale of the world anti-doping (the code) which ''seek to protect the health of athletes and to provide the opportunity for athletes to pursue human excellence without the use of prohibited substances or methods'' (WADA,2020b).critics of the health justification for anti- doping policy point out that sport itself can be inherently dangerous[4]. The enforcing product bans and recalls is particularly problematic in developing countries because Herein one experience a gap between passing a ban or recall policy on paper and the real world implementation of the policy given resource constraints and lack of liability laws .In case of a drug ban , although the resolution to ban a drug is passed in court of law and by health authorities ,whether it is implemented, and how quickly the policy permeates to the marketplace crucially depends on the market structure and the supply chain [5]. FDA makes good decisions when they approve a good drug in a reasonable amount of time that is effective and safe[6].

REASONS:

Drug is introduced into the market for benefit of consumers. The main aim is to ensure a good quality of life for patients but every drug comes with its own adverse effects. Before the egrouse test passing in manufacture'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[1]. Drugs undergoes rigorous testing before they are introduced into the market. Efficiency as well safety profile has been detected [7]. These causes several adverse effects, excess toxicity, availability, of safer alternatives, harmful interactions, 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. 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[1].A number of single drugs as well as fixed dose combinations have been banned from manufacturing, marketing and distribution in India .An important issue about the availability of banned drugs over the counter in India is that sufficient adverse drug reactions data about these drugs have not been reported[8]. There is a substantial body of literature documenting the adverse effects of PED misuse. These publications are almost exclusively retrospective case studies with the vast majority documenting adverse effects of AAS abuse in amateur or recreational athletes. A sampling is this literature includes case reports detailing jaundice in a 24- year-old amateur body builder injecting a Veterinary product, renal damage from uncontrolled use of multiple AAS in body builders so that's why the PED or banned but in India some drugs are used[4]. Antibiotic fixed dose combinations (FDCs) will have medical benefits which include enhancing effectiveness and adherence to therapy. High use of probably in suitable FDCs has been reported, with implications for antimicrobial resistance (AMR) and toxicity [9]. Public forums however, by far the most common rationale offered for banning supposed health aids is public interested concern about consumer ignorance about product quality[10] .

PHARMACOVIGILANCE:

Pharmacovigilance is the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long-term and short-term side effects of medicines. "Drug controller general of India'' is the highest authority in India to expand the approval of any drug or to ban a drug. If any is to have harmful side effects, the government issues the ban order and all manufacture and wholesaler are asked not to stock the particular medicines. 'If doctors stop prescribing drugs that are harmful to patients" health, chemists will automatically stop selling since the are no patients asking for it, and hence, manufacturers do not produce it. Certainly, many of the problems can be solved like that the manufacturers every reason to sell their products[4].

DRUG WITHDRAWAL IN PHARMACOVIGILANCE

This is the main aim to withdrawal of drug because of adverse effects. The data base of drugs that have been withdrawn from the market worldwide, or whose labeling has been changed, is very large. Drugs may be withdrawn, never to return. others are withdrawn but then reappear with a risk management plan. In some cases, a new formulation is withdrawn but the drug itself continuous to be made available; in some cases, it is the route of administration that is abandoned. Studies reveal that the liver is the most common organ to be affected by the most common organ to be affected by drugs whose licensing or labeling status is subsequently changed. However, effects on the liver do not have a strong predictive value of the risk of such changes, because other systems are also often affective. There is no one group of drugs that emerges as being particularly likely to suffer, although it is better to be cautious with new NSAIDs and psychotropic drugs, which feature commonly. The delay in discovering serious adverse effects of new drugs is becoming encouragingly shorter, which suggest that pharmacovigilance techniques are paying off, at least where serious adverse effects are concerned[11].

REASONS FOR DRUG WITHDRAWAL**:**

The withdrawal of a particular institution or clumps of a product from the marketplace is probably occasioned with the aid of using the accompanying:

1.Serious reviews of detrimental drug reactions now no longer protected with inside the package deal in
2.Unexpected frequency of detrimental response said with inside the package deal insert.
3.Incorrect labeling of a product.
4.Incorrect components of a product.
5.Result of ongoing balance studies.

PROCESS OF DRUG WITHDRAWL:

At the factor while a tough problem takes place in human offerings there may be dependably an "automatic" response through several people pressure a withdrawal and consequently deliver a ban and entire response to the problem. While such reactions are probably candidly pleasing, they often talk to solutions which are "extra astute then we are" and might land up inflicting extra harm then whatever else. The exemplary case of medicine prohibiting has been the journey of Thalidomide. Thalidomide created in Germany with inside the mid 1960's, ended up widely known on an average premise as a sedative and relaxation promoting medicine. Thalidomide at the beginning seemed, through all accounts, to be sheltered. The fact turned into a teratogen (suit for delivery absconds) associated with development of fetal furthest points. By chance, there may be no fundamental manipulate on hand until date forbidding of medicinal drugs on the equal time in all nations. The drug Technical Advisory Board (DTAB) in India is the final professional on forcing on forcing a ban. A reliable board inspects the hazardous influences of the medicinal drugs and reviews the results to the DTAB. In the occasion that any medicinal drugs are observed to harmful reactions, the Government problems the boycott officials on the Drug controller of India (DCGI) office, be that because it may have an exchange interpretation of the problem of restrained medicinal drugs. "Screening of drug or harmful medicinal drugs is a non-stop workout and extra than seventy-nine classifications of plans had been restrained up till now. With a view to making sure valid apportioning and goal usage of medicinal drugs, urgent has been institutionalized Indeed, even after a medicinal drug receives promote it endorsement, safety and viability is continuously inspected primarily based totally on records were given through pharmacovigilance, post marketing commentary and records were given from special nations. India's dedication to the general amassing of statistics as an afterthought influence of diverse medical drugs is troubling. Nations like Ireland, Switzerland, and Italy with a population of round 4million, 33million and 57million individually, had submitted 25, 33 and 225 unfriendly medicinal drug response on Nimesulide. Inspite of average boycott medicinal drugs, for example Nimesulide, phenyl propanolamine, Analgin, and so on are 27 being offered in India. At the factor while a completely useful medicinal drug is illegitimate overseas for its unfriendly influences, intrigue bunches in India oppose similar past time hear[12].

DRUG RECALL IN PHARMACOVIGILENCE

The pharmaceutical industries primary concern is to provide high –quality drug products to the general public, so Drug recollects play a crucial function in retaining the best device with the aid of using casting off faulty merchandise from the market. Pharmaceutical product recalls are increasing at an alarming rate because of increased inspection rates and the introduction of modernization and the digital world into the industry, raising concerns for regulatory agencies and public health to focus on more stringent regulations to control future recalls of defective drug products. This article will provide an overview of recall procedures, their impact on the pharmaceutical industry, and the various steps taken to reduce pharmaceutical recalls[13].

Medical devices are usually conducted voluntarily by the manufacturer under 21CFR7. In rare instances, where the manufacturer or importer fails to voluntarily recall order to the manufacturer under 21CFR810, medical device recall Authority. 21CFR810 describes the procedures the FDA will follow in exercising its medical device recall authority under section 518 of the Federal food, drug, and cosmetic Act under 21CFR806, medical device correction and removals, manufacturers and importers are required to make a report to FDA of any correction or removal of a medical devices. If the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the Act caused by the device which may present a risk to health.

RECALL CLASSIFICATION

Recalls are classified into a numerical designation (I, II, or III) by the FDA to indicate the relative degree of health hazard presented by the product being recalled.

- Class I- A situation in which there is a reasonable probability that the use of, or exposure to, violative product will cause serious adverse health consequences or death.
- Class II - A situation in which or use of exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

- Class III -A situation in which use of or exposer to a violative product is not likely to cause adverse health consequences.

RECALL STRATEGY

The recalling firm should develop a recall strategy that considers the following factors as they apply individual circumstances of the particular recall:

- Results of health hazard evaluation.
- Degree to which the product 'deficiency is obvious to the consumer or user.
- Easy to identify the product. Degree to which the product stays unused withinside the marketplace.
- Continued availability of crucial products.

The FDA will review the adequacy of the proposed recall strategy and recommend changes as appropriate. A recalling organisation ought to conduct the endure in thoughts in accordance with an authorized endure in thoughts strategy but need now not put off initiation of a don't forget pending assessment of its don't forget strategy.

A remember strategy will deal with the subsequent factors concerning the behavior of the remember:

1. DEPTH RECALL: depending on the product's degree of hazard and extent of distribution chain to which the recall is to extend, as follows:

- Consumer or consumer level, which might also additionally range with product, consisting of any intermediate wholesale or retail level.
- Retail level, including any intermediate wholesale level.
- wholesale level.

2. PUBLIC CAUTION: The reason for public caution is to alert the general public that a product being recalled provides an extreme risk to health. This is reserved for urgent situations where other means for preventing use of the recalled product appear indicated. The FDA in consultation with the recalling business enterprise will more often than not have a problem with such publicity.

- General public warning through the general news media, either national or local as appropriate.
- Public warning through specialized news media, e.g., professional or trade press, or to specific segments of the population such as physicians, hospitals etc.

3. EFFECTIVESNESS CHECKS: the purpose of effectiveness checks is to verify that all consignees have received notification about the recall and have taken appropriate action. Consignees may be contacted by personal visits, telephone calls, letters, or combination there off. A guide entitled "Method for conducting recall effectiveness checks" that describes the use of these different methods is available from FDA. The recalling firm will ordinarily be responsible for conducting effectiveness checks, but FDA will assist in this task Where necessary and appropriate. This method will specify the strategies for use for and the extent of effectiveness tests in an effort to be conducted, as follows:

- Level A-100 percent of the total number of the consignees to be conducted;
- Level B-some percentage of the total number of consignees to be conducted, which percentage is to be determined on a Case-by-case basis, however, is more than 10 percentage and much less than a hundred percentage of the entire quantity of consignees;
- Level C-10 percent of the complete extensive kind of consignees to be contacted;
- Level D-2 percent of the total number of consignees to be contacted;
- Level E -No effective[14].

In this recall strategy the effectiveness of the drug is noted and can be easily determined the toxicity of the drug. Recalling of the drug are very important in banning of the drug it contains different strategies for determine the amount of the toxicity .

PHARMACIST ROLE IN DRUG ABUSE

In 2019 there had been about 332,000 pharmacists lively withinside the US Work force, Data USA, 2019.A survey of 1700 American adults, discovered, that 34% of Americans nonetheless depend on health care providers such as pharmacists, for information in relations their health, KRC Research, 2018. Pharmacists are one of the 3 maximums depended on fitness care professions and had been discovered to be the second one maximum depended on supply for fitness records with the aid of using Americans in 2005. Blendon al 2006 found, that information from pharmacist was trusted by 67% of participants in their survey. One of the Oaths pledged through pharmacist is 'I will observe my knowledge, experience, and abilities to the best of my ability to assure optimal outcomes for all patients AACP Board of Directors and the APHA Board trustees, 2021. In recent times however this is the goal still optimal outcomes for patients, or optimal outcomes for sustained revenues. The average Americans visits their pharmacy 775% more times, than their primary health care provider. It is pretty

alarming though, that pharmacists spend on common simplest 10%in their days with their patients, Gebhart, 2019. Them exists an exponential opportunity for pharmacists to help curb the $35 billion drug abuse cost. Approximately, fifty-three million Americans have used or misused prescription drugs, National median for drug abuse statistics
,2022. Annually, 16.3 million Americans misuse prescriptions, with 3.7 million misuses going on with first time users, National center for drug abuse,2022. Pharmacists may help to reduce prescription misuse. This movement may be taken via education, best time, training, and consistency with the usage of drug tracking programs.

PHARMACIST SPENDING QUALITY TIME WITH PATIENTS

The role of the pharmacists as 'trusted sources' for information by many Americans, is one solution to lessen the drug abuse epidemic. Increased pharmacist to affected person interplay is required, to offer fine care, rather than aiming to attain a day-by-day goal of prescriptions to be filled. By growing time spent with patients: clean commands on the way to use an excessive first-class drug may be taught, with extended hobby of noticeably addictive drugs, prevention methods, opportunity and coping techniques, effects of sharing medication, garage and disposal of pharmaceuticals may be communicated. Many pharmacies have "take-again days" and the DEA additionally has legal locations, where patients are encouraged to take back their unused medications for proper disposal, DEA, SAMSHA,2017. Quality time, in addition to having united interactive and educational program, will help communities to identify abuser behaviors, signals for prescription misuse, signals for Prescription misuse, signs and signs of overdose, control of naloxone (opioid antagonist), and issue effects to prevent further addition to the modern-day drug abuse burden, samhsa, 2017[15].

PHARMACEUTICAL REGULATIONS AND GUIDELINES IN INDIA

The rationale for pharmaceutical regulation is imperfect or asymmetric information. Evidence about drug safety and efficiency is difficult to observe and evaluate. As a consequence, physicians and patients lack information about a drug's quality. Information about the benefits, risks, and overall performance of a new drug is critical for their safe and effective use. Without accurate information about drug quality, physicians and patients may make inappropriate drug choices and suffer negative health consequences. The adulteration of drug products and detrimental effects on public health were motivated forces for developing early pharmaceutical regulations. Pharmaceutical products and their effects have become increasingly complex over time and evaluating those effects requires special expertise. Expert agencies like the FDA and the European Medicines Agency (EMA) regulate the prelaunch data requirements and evaluate the evidence over the life of a drug, to reduce the effects of informational asymmetries and uncertainty in pharmaceutical market. Regulators strive to protect public health [16].

PURPOSE OF GUIDELINES :

The Guidelines are introduced to aid in formulating national legislations and polices for prescribers, pharmacist's law enforcement authorities, regulatory authorities, and the public with regard use of prescription to dispense the drug [17].

REGULATORY STATUS OF BANNED DRUGS IN INDIA

'PILL FOR EVERY Ill's 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 patients' life more comfortable to greater extent. The aim is to ensure a good quality of life for the patients. This can only be achieved with quality of drugs with maximum therapeutic benefit and minimum side effects, available to all low cost. An affected man or woman is primarily based totally on his doctor and prescriber for his treatment. Thus, it is the duty of patients to meet the patients' requirements to their satisfaction. Analgin turned into extensively used, without difficulty available, distinctly cheap, and efficacious analgesic. Initially this drug turns out to be banned in 1974 because of the myelotoxicity but big methodological flaws in the study led to criticism and the drug was unbanned in 1995 but as a prescription drug only. Further studies led to more controversies regarding its association with agranulocytosis and it was again 6 withdrawn from market in 1999. It was estimated that fetal agranulocytosis occurred in one out of 10,000users of the drug Analgin.

REASONS OF AVAILABILITY OF BANNED DRUGS IN INDIA

A lengthy legal procedure to ban any drug in India which is banned in developed countries gives long time to manufactures to manufacture these banned drugs in India. Commercial interest of pharmaceutical companies, corruption, lack of transparency and accountability is the major reason of such delay in 28 banning. Regulatory bodies lack enforcement power.

1. Due to the poverty line in India these drugs are easily marketed at low costs.
2. Many private practitioners and physicians are unaware about the ban more than 30 drugs are banned.

PROCESS OF DRUGS BAN IN INDIA

When a serious problem occurs in health care there is always a "KNEE JERK" responses by many to impose a ban and thus provide an immediate and definitive responses to the issue. While such responses can be emotionally satisfying, they regularly constitute solutions which are "smarter than we are" and might emerge as inflicting greater damage than good. The classic example of drugs banning has been the Thalidomide. Thalidomide developed in Germany in the mid 1950's became popular on a worldwide basis as a tranquilizer and sleep-inducing medication. Thalidomide initially appeared to be safe. The fact was that it was a teratogen (capable of birth defects) associated with maldevelopment of fetal extremities The Drug Technical Advisory Board (DTAB) India is the final authority on imposing a ban. An executive committee examines the harmful effects of drugs and reports the results to the DTAB. If any drug is found to have harmful side effects the government issues the ban order and all manufactures and wholesalers are asked not to stock the banned drug[18]

Table-1

List of prohibited drugs in India

s.no	Drug Name	Notification No. & Date
1	Amidopyrine	GSR No. 578(E) Dated 23.7.1983
2	Nialamide	GSR No. 578(E) Dated 23.7.1983
3	Phenacetin	GSR No. 578(E) Dated 23.7.1983
4	Practolol	GSR No. 578(E) Dated 23.7.1983
5	Methapyrilene, its salts	GSR No. 578(E) Dated 23.7.1983
6	Chloral hydrate as a drug	GSR No. 304(E) Dated 07.6.1991
7	Dovers's powder I.P	GSR No. 612(E) Dated 09.8.1994
8	Dovers's powder Tablets I.P	GSR No. 612(E) Dated 09.8.1994
9	Fenfluramine	GSR No. 499(E) Dated 14.8.1998
10	Dexfenfluramine	GSR No. 499(E) Dated 14.8.1998
11	Astemazole	GSR No. 191(E) Dated 05.3.2003
12	Terfenadine	GSR No. 191(E) Dated 14.8.1998
13	Phenformin	GSR No. 780(E) Dated 1.10.2003
14	Rimonabant	GSR No. 884(E) Dated 11.12.2009
15	Rosiglitazone	GSR No. 910(E) Dated 12.7. 2010
16	Paracetamol + Phenylephrine + Caffeine	S.O No.713 (E) Dated 10.3. 2016
17	Amoxicillin + Bromhexine	S.O No. 777(E) Dated 10.3. 2016
18	Pholcodine + Promethazine	S.O No. 789(E) Dated 10.3. 2016
19	Imipramine + Diazepam	S.O No. 795(E) Dated 10.3. 2016
20	Nimesulide + Diclofenac	S.O No. 4380(E) Dated 7.9. 2018
21	Nimesulide + Cetirizine + Caffeine	S.O No. 4381(E) Dated 7.9. 2018
22	Azithromycin Cefixime	S.O No. 4422(E) Dated 7.9. 2018
23	Nimesulide + Pseudoephedrine + cetirizine	S.O No. 256(E) Dated 11.1. 2019
24	Ofloxacin + Diclofenac + Lignocaine	S.O No. 257(E) Dated 7.9. 2019
25	Ondansetron + Omeprazole	S.O No. 258(E) Dated 7.9. 2019
26	Hydrochlorothiazide + Ramipril + Losartan potassium	S.O No. 259(E) Dated 7.9. 2019

27	Fixed dose combinations of corticosteroids with any other drug excluding FDC of Tamsulosin HCL 0.4mg + Deflazacort 30mg in hard gelatin capsule	Substituted vide GSR No 255(E) date 7.4.2021
	for internal use expect for preparations meant for metered dose inhalers and dry powder inhalers.	
28	Fixed dose combinations of Salbutamol + Bromhexine for human use	S.O No. 2405(E) Dated 2.6. 2023
29	Fixed dose combination of Phenytoin + Phenobarbitone	S.O No. 2406(E) Dated 2.6. 2023

BANNED ON FIXED DOSE COMBINATIONS

A combination of two or more active ingredients in a fixed ratio of doses, combined to form a single pharmaceutical dosage form a signal pharmaceutical dosage form a signal pharmaceutical dosage form is known as FDC. USA defines a difficult and speedy dose combination product "as a product composed of any combination of a drug and device or natural product for a treatment". In general, fixed dose combination of two or more active pharmaceutical ingredients or compounds formulated as a single medicine irrespective of its dosage form designed Here, the product is composed of two or more ingredients that are in a fixed composition ratio or particular dose, hence he terms fixed ratio or dose combination is termed [19].

CONCLUSION:

Drugs are designed to be life savers. Due to reporting of harmful adverse effects some drugs are banned. A ban is needed to protect the public's health and quality of health care. Most of the drugs are banned in other countries for proven adverse effects but still available in India. These are due to lack of awareness and used the banned drugs as over the counter drugs and causes severe harm to their health. There for it becomes important for the government to implement strict laws on manufacturers, wholesalers, and retailers. And government should be ordered to dump these cheap drugs in proper manner and also there should be creating awareness amongst physician, health professionals and general public about the ADR of these drugs and thus play an important role of eliminating the banned drugs from market.

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