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DRUGS BANNED BY FOOD AND DRUG ADMINISTRATION(FDA)

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ABSTRACT

Drugs which are unauthorized in abroad are comfortably available in India. The most pitiful aspect is that daily usage of these medicines has long-term consequences for our physical health. Unawareness, a lack of law enforcement, and corruption are all factors that contribute to drug usage. India has become a dumping ground for illegal drugs, and the industry of producing them is increasing as well. All of the formulations are for the prevention or treatment of disorders and diseases, with only a few vital drugs, and the rest interchangeable. Due to a lack of law enforcement physician awareness and the drug control authority's failureto inform all hospitals of the status of medicine, banned substances are nonetheless available in underdeveloped nations like India. Unfortunately, anti-diarrheal, analgesic and cough medicines that are illegal in other countries are sold as over-the-counter medicines in India. The Indian government is working on a regulatory framework to guarantee that medical gadgets are of high quality, safe, and operate well. Pharmacists should take an active role in public awareness efforts and consumer education since they can help to remove prohibited medications from the market.

KEYWORDS: Illegal Drugs, FDA, Banned Drugs, Unauthorised drugs, Indian Drugs.

INTRODUCTION

The "Drug Controller General of India" is India's top authority when it comes to approving or banning drugs. Some of the deadly medications have been banned worldwide, yet they are still available in India. Banned medicines are those that are not permitted to be consumed because they may be used to artificially increase performance and have more negative side effects than therapeutic effects. Whose manufacture or use is forbidden or highly regulated by prescription.

A drug is defined as "a chemical or synthetic substance used in the treatment, prevention, or diagnosis of disease, or to improve physical or mental well-being in some other way."

Why in India drugs are used as they are already banned?

India is becoming open gate or door for irrational drug market

Because there are more users here and all illegalities are dutifully obeyed, the business of producing prohibited medicines is booming. India has turned into a heaven for illegal substances.

The irony is that few people are aware of the restriction.

Pharmaceuticals have grown in every direction as big-time business operations and small-time defaulters. In Indian markets, there are limited provisions for a proper check and control of counterfeit medications.

Worse than that, the customers' lack of information and sloppy attitude.

Even now, a substantial portion of the public consumes medicine and pharmaceuticals withou t first consulting a doctor, which is a really poor decision that can be harmful.

Drugs like Analgin, Cisapride, Nimesulide, and Piperazine, which have been recalled around the world due to terrible side effects, are among the top sellers in India, thanks to a nearly "missing" adverse drug reaction mechanism. According to a World Health Organization report, there hasn't been a single incidence of an adverse drug response reported in the country. In India, the business of producing these abandoned medications is flourishing.

Nise (Dr. Reddy's) and Nimulid (Panacea Biotech) are two of the most frequent, both of which have been recalled due to reports of liver damage, while Vicks Action 500 from Procter and Gamble has been recalled due to an increased risk of brain haemorrhage.

Droperol, a triokka-produced antidepressant, has been withdrawn from the market due to irregular heartbeats in patients.

After reports of cancer in some individuals who were given the anti-diarrhoeal medicine Furoxone (from Glaxo), the drug was pulled from the market. Eleven medications, including cisapride, furazolidone, nimesulide, and phenylpropanolamine, are still on the market in India despite being banned, withdrawn, or marketed with limitations in North America, Europe, and several Asian nations.

India's contribution to the global series of statistics at the facet outcomes of various pills is dismal. Countries like Ireland, Switzerland and Italy with a populace of approximately four million, 33 million and fifty seven million, respectively had submitted 25, 33 and 225 unfavourable drug response on nimesulide. However, India, with over 1 billion populaces did now no longer document any. Another drug Sildenafil (erectile disorder drug) had 18 unfavourable drug reactions said from Australia however none from India.

According to a source from the Ministry of Health, monitoring of adverse drug reactions is not followed in the medical student curriculum in India, and most doctors do not keep patient records. medical opinions exposing the deep flaws prevalent in the drug approval process in India. The committee found that an "overwhelming" majority of drugs were approved on the basis of personal prescriptions and without any scientific evidence.

Thus, final records are clearly shows The Documents which consists merely signed by experts. On the contrary, invisible hands of drugmakers are always in action.

Of the 42 drugs tested, 11 were approved without undergoing a phase III clinical trial to validate their safety and efficacy. Between January 2008 and October 2010, CDSCO conducted 33 new drugs (Cipla Ltd's colistimates and pirfenidone, Novartis Pharmaceutical's aliskiren, and GlaxoSmithKline's ambrisentan) without conducting clinical trials, according to the Commission's findings. Approved (including) and approved 25 medications without consulting a qualified doctor.

It also found that four drugs (everolimus from Novartis, buclizine from UCB Biosciences Inc., pemetrixid from Eli Lilly and Co. and a fixed-dose combination of pregabalin from Theon Pharmaceuticals) were approved by "CDSCO non-medical staff" without the mandatory clinical trials or medical expert opinion and that 13 drugs were effectively banned in developed countries.

Safety of patient’s health and proper efficacy of medication is the part and parcel pharmacy field and hence everyone is bound to follow it by hook or by crook.

Drugs recall by FDA

Receiving the drug from market this process generally called “Product recall”. Drug recall is the best way to secure public health from dangerous or toxic drug substances. If any pharmaceutical product contain any toxic or harmful moiety is present then the recall process

is initiate. It is a voluntary action of company to remove the defective product. Recall process may be initiated by companies own initiative or by request of FDA.

1. **Rofecoxib (vioxx) :-** Time on the market 1999-2004.

This specific nonsteroidal antiinflammatory drug (NSAID) for arthritis was linked to over 28,000 heart attacks in the US population between 1999 and 2003.

According to the researchers, the medicine caused four heart attacks per 1,000 people who took it.

Merck, the company that made it, unilaterally removed it from the market in 2004. This medicine was provided to almost 20 million people in total.

2. **Valdecoxib (Bextra)**

Valdecoxib is a nonsteroidal anti-inflammatory drug (NSAID) that the FDA later determined did not work any better than other NSAID pain relievers on the market. The drug was recalled due to a higher risk of serious skin reactions like epidermal necrolysis, erythema multiforme, and Stevens-Johnson syndrome, as well as an increased risk of death, heart attack, and stroke. Furthermore, the medicine included the risk of causing gastrointestinal hemorrhage.

3. **Troglitazone (Rezulin)**

Time on market – 1997-2000

This antidiabetic and anti-inflammatory medicine caused 90 incidences of liver failure and at least 63 fatalities in people who took it.

It also resulted in 35,000 lawsuits against Parke-
Davis/Warner Lambert, the company that manufactured it (now Pfizer).

4. **Efalizumab (Raptiva)**

Years on the market – 2003- 2009

This biologic was originally approved to treat psoriasis, but it was recalled after it was discovered to cause progressive multifocal leukoencephalopathy, a rare and fatal condition characterised by inflammation and damage to the brain's white matter and central nervous system.

After receiving complaints or data warranting the withdrawal of a product from the market, manufacturers normally undertake voluntary recalls at the FDA's request and with the FDA's

cooperation.

Manufacturers will typically discontinue supplying the medicine entirely at thispoint.

The aminopyrines were first used as analgesics and antipyretics around a century ago, but it wasn't until the 1930s that agranulocytosis, their most common side effect, was discovered.

Although agranulocytosis is the most common blood dyscrasia in individuals using aminopyr ines, aplastic anaemia has also been recorded.

For these reasons, most developed countries have prohibited or withdrawn certain medication s from the market.

Aminopyrines, on the other hand, are still available in many parts of the world, including the Far East, Africa, and Latin and South America, and are used as adulterants in some 'herbal' pa tent treatments.

5. Pemoline (Cylert)

Time on the market – 1975-2010

This central nervous system stimulant is used to treat ADD and ADHD (Attention Deficit Hyperactivity Disorder). In 1999, the FDA added a boxed warning about possible causes of liver damage. After that, a recall was made.

6. Bromfenac (Duract)

Time on the market – 1997- 1998

In the year it was on the market, this pain reliever resulted in four deaths, eight liv er transplants, and twelve cases of serious liver damage.

The medicine was only supposed to be administered for ten days, but patients were frequently given higher doses. Patients who took the medicine for more than10 days died or developed liver damage in every case.

7. Terfenadine (Seldane)

Time on market – 1985- 1998

This antihistamine was recalled because it caused deadly heart problems when combined with erythromycin or ketoconazole.

The medicine was subsequently taken from the market because its maker, Hoechst Marion

Roussel (now Sanofi-Aventis), also sold fexofenadine (Allegra and Allegra-D), which the FDA regarded to be a far safer option.

8. Amidopyrine

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9. Phenacetin

Harmon Northrop Morse, an American scientist, invented phenacetin in 1878. In 1887, it was first presented to the pharmaceutical market. In the United States, ho wever, it was discontinued in 1983 because to inadequate levels of interstitial nep hritis in patients and probable tumorigenicity hazards.

Because it causes kidney illnesses and malignancies of the upper urinary tract, phe nacetin, a commonly used painkiller, has been banned in most nations since the late 1960s.

10. Nialamide

Nialamide (Niamid, Niamide, Nuredal, Surgex) is an antidepressant that is a non- selective, irreversible monoamine oxidase inhibitor (MAOI) of the hydrazine class Pfizer pulled it off the market decades ago because of the danger of hepatotoxicity.

11. Methaqualone

In the 1980s, the FDA classed methaqualone as a Schedule I narcotic, a highly add ictive chemical with no current medical necessity in the United States, in an attempt to rein in its use. Its manufacture as a legitimate medicine has been suspended.

AUTHORITIES RESPONSIBLE AND GOVERNMENT AWARENESS

The DTAB (Drug Technical Advisory Board), which is the final authority on placing a ban, is in charge of the process of banning drugs in India. The Indian Drug Controller General notifies all state substance agencies and manufacturers of the drug's prohibition. This section contains key Indian and international rules and regulations.

CDSCO	The Ministry of Health & Family Welfare's Central DrugsStandard Control Organization (CDSCO) provides broad information on drug regulation requirements in India.
D and C act 1940	The Drugs and Cosmetics Act of 1940 governs drug importation, manufacture, distribution, and sale in India
Schedule M	The D&C Act's Schedule M lays out the general and specialized standards for factory premises and plants, materials and equipment, and minimum suggested areasfor basic installation for specific drug categories.
Schedule T	GMP criteria for Ayurvedic, Siddha, and Unani medicinesare prescribed under Schedule T of the D&C Act.
Schedule Y	Specifications of Schedule Y of the D&C Act guide theclinical trials' statutory requirements.

Important international norms and regulatory agencies are linked.

WHO (Medicines)	WHO guidelines on pharmaceutical policy, intellectual property rights, financing and supply management, qualityand safety, medication selection and rational usage, technical cooperation, and traditional medicines.
ICH	Quality, safety, efficacy, and associated elements for developing and registering new pharmaceutical goods inEurope, Japan, and the United States are defined by the (ICH) guidelines.
EMEA	The European Pharmaceuticals Agency (EMEA), based inLondon, is a decentralized authority of the European Union that establishes criteria for inspections, general reporting, and other aspects of human and veterinary medicine in the EU.
TGA	Therapeutic Goods Administration, an Australian regulatory organisation, publishes specifications governingpharmaceuticals, medical equipment, blood, tissues, and chemical
WTO	World Trade Body (WTO) news, resources, documents, and publications. The World Trade Organization (WTO) isa global international organisation that deals with international trade rules.
Thai FDA	Drugs, food, cosmetics, and narcotics are all covered by Thai Food and Drug Administration laws and regulations.
DGMP Belgium	The Belgian Directorate-General Medicinal Products hasissued guidelines and relevant information to assure the safety, efficacy, and quality of medicines.
BfArM, Germany	The German Federal Institute for Drugs and MedicalDevices has established licencing and registration guidelines for medicinal items.
OECD	Economic and social challenges in health care are addressed through the Organization for Economic Collaboration and Development, which has 30 membernations.
US FDA	US Food and Drug Administration regulations, policies,notices, news, and communications.
South Africa	South African Ministry of Health.
Codex Alimentarius	A collection of international food standards and guidelinesfor processed, semi-processed and raw foods adopted by the Codex Alimentarius under the FAO / WHO Joint FoodStandards Program.
MHRA	News, alerts, information, and publications from the Medicines and Healthcare Products Regulatory Authority(MHRA), responsible for ensuring the efficacy and safetyof UK medicines and medical devices.
Medsafe, New Zealand	Medsafe, New Zealand Pharmaceutical and MedicalDevice Safety Authority
NPCB,	Regulatory information, news and publications fromMalaysia's National

Malaysia	Pharmaceutical Administration.
MPA, Sweden	Regulatory and monitoring guidelines issued by theSwedish Medical Products Agency

SUMMARY AND CONCLUSION

For outlawed drugs that aren't pleased prescription-controlled substances, some critics believe that illegal recreational use is inherently irresponsible; thanks to the unpredictable and unmonitored strength and purity of medication are the risks of addiction, infection, and alternative aspect effects. Though every country has its own list of illegal medication, it is worrisome that some drugs that are banned in alternative countries for established adverse effects are still on the market in the Indian market. a number of these drugs are available over – the – counter and other people might take it while not realizing the risk. The Central medication customary management Organisation run by the govt of Asian nation has got to create a strict pointer over the list of drugs are banned by world organisation and USA. A note of caution on these drugs might facilitate patients to decide whether or not they need to require the drug. Please confirm that patients obtain drugs providing prescribed by a doctor. which additionally from A reputed drug store. Not many folks realize these illegal drugs and consume them inflicting tons of injury to themselves.

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