



Banned, for real?

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ABSTRACT

A drug is any chemical agent that affects the living organism. Authorities like the US-FDA and CDSCO are responsible for the approval and post-marketing surveillance of drugs. Many a times, a life-threatening side effect may occur after the drug has been introduced in the markets. Here, prompt action is of utmost importance. However, despite being banned, certain drugs tend to prevail in the markets and pose a danger to the healthcare system. The purpose of this articles is to elaborate the availability of certain banned drugs available on the Indian market.

KEYWORDS : Banned drugs, CDSCO, India

Introduction

A 'Drug' is defined as any chemical agent that affects living protoplasm [1]. The effect on this 'living protoplasm' may be beneficial or harmful, in accordance with the characteristics of the drug as well as the concerned organism. Countless factors play a role in the proper functioning of a drug, ranging from the dose of the drug to the genetic make-up of the organism. Various authorities, like the Food and Drug Administration (FDA), United States of America and the Central Drugs Standard Control Organization (CDSCO), India, are responsible for looking over the approval, marketing and post-marketing monitoring of the drugs. On rare occasions, an approved and marketed drug may have a deleterious effect on the individual using it, which can be caught only after the drug is brought to use in the general population since clinical trials, per se, are conducted in controlled environments. In such a situation, prompt reporting of the event becomes crucial. Reporting, however, in itself is not sufficient. An in depth scrutiny of the drug and supervision of the individuals using it is equally essential. Depending on the results, a drug then may either be withdrawn, banned or supplemented with a warning, the black box warning.

Light was shed on the deleterious effects of drugs after the Thalidomide disaster in 1960s, where babies were born with limb abnormalities [2]. New laws were introduced and implemented to prevent further tragedies. Also, post this event, 'n' number of drugs were withdrawn as well as banned worldwide. In certain situations, a drug may be banned only in a particular country and be freely available, with or without prescriptions, in others. However, once banned, a drug cannot be manufactured and sold in the respective country.

Materials and Methods

A thorough online search was done using Google to access the date and cause of drugs banned by the CDSCO in India.

Results

Despite stringent rules and regulations, a great number of banned drugs are still available in India, the reason for which remains unknown. Drugs that are banned in India are listed in Table 1, along with the brand name, year and cause of the ban [3]. Similarly, Drugs available in the Indian market, despite being banned, are listed in Table 2 [4].

Table 1: List of Drugs Banned in India

Sr. No.	Drug Name	Year of Ban in India	Cause of Ban
1	Amidopyrine/Aminophenazone	1983	Agranulocytosis, Aplastic anemia
2	Phenacetin	1983	Carcinogenesis, renal damage (failure)

3	Benzy-Penicillin ointment	1983	Skin lesions, pruritus
4	Tetracycline, Oxytetracycline, Demeclocycline - liquid oral preparations	1983	Intracranial hypertension, pericarditis. Metabolic disturbances like hypoglycaemia. Bone defects In children.
5	Practolol	1983	Oculomucocutaneous syndrome
6	Methapyrilene	1983	Liver cancer in rodents
7	Methaqualone	1983	Dependence, peripheral neuritis
8	Fenfluramine	1998	Cardiac fibrosis, pulmonary hypertension
9	Dexfenfluramine	1998	Cardiovascular side effects
10	Astemizole	2003	Cardiovascular side-effects with anti-fungal drugs
11	Terfinadine	2003	Cardiovascular side-effects with anti-fungal drugs
12	Phenformin	2003	Lactic acidosis
13	Valdecobix	2005	Cardiovascular side-effects
14	Rimonabant	2009	Depression, Suicidal tendencies
15	Rosiglitazone	2010	Cardiovascular side-effects
16	Nimesulide in children below 12 years	2011	Liver failure
17	Cisapride	2011	Arrhythmias
18	Phenylpropanolamine	2011	Stroke
19	Sibutramine, R-sibutramine	2011	Heart attacks, stroke
20	Gatifloxacin - Oral and Injectable	2011	Dysglycemia
21	Tegaserod	2011	Heart attacks, stroke
22	Letrozole, for ovulation induction	2011	Locomotor and cardiac abnormalities in the child
23	Dextropropoxyphene	2013	Arrhythmias

24	Analgin/Metamizole/Dipyrone	2014 (revoked)	Agranulocytosis, Aplastic anemia
25	Pioglitazone	2013 (revoked)	Bladder cancer
26	Human placental extract except topical application for wound healing and as an injection for pelvic inflammatory disease	2011	Transmission of infections, Heart attacks, stroke

Table 2: Drugs available in India, despite being banned

Sr. No.	Drug Name	Available as
1	Dexfenfluramine	Redux
2	Astemizole	Acemiz, Stemiz
3	Valdecoxib	Artival
4	Rimonabant	Ribafit
5	Rosiglitazone	Reglit
6	Nimesulide in children below 12 years	Nise, Nimulid
7	Cisapride	Ciza, Syspride
8	Phenylpropanolamine	Vicks Action 500
9	Sibutramine	Leptos
10	Gatifloxacin - Oral	Algat, Amgat
11	Tegaserod	Ibsinorm
12	Dextropropoxyphene (As a Fixed Drug Combination)	Colidex
13	Analgin/Metamizole/Dipyrone	Novalgin
14	Pioglitazone	Pioz

Conclusion

It won't be erroneous to conclude that, almost, one half of the drugs that have been banned in India are still being produced and are easily available in the market. In the presence of better and safer drugs, subjecting the general population to known dangerous medications is unethical. At the same time, a burden will remain on the healthcare system, anticipating the occurrence of serious adverse effects. Whether the neglect is on the part of the authorities, the industry or the prescribing physicians, cannot be easily determined. The only way to prevent future catastrophes is a strict vigilance and prompt action, if the need arises.

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References

1. Bruton LL, Chabner BA, Knollman BC. Goodman & Gilman's The Pharmacological Basis of Therapeutics. 12th ed. The McGraw-Hill Companies, 2011.
2. Kim JH, Scialli AR. Thalidomide: The Tragedy of Birth Defects and the Effective Treatment of Disease. *Toxicol. Sci.* 2011;122(1):1-6.
3. 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. Available at <http://www.cdsc0.nic.in/> as accessed on 20.12.2016.
4. Brand name of drugs in India. Available at <https://www.drugs.com/> as accessed on 20.12.2016.