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Review Article

Regulatory Control on Banned Drug: A Review Article

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ABSTRACT

A Number of drug that are banned in abroad are freely available in the Indian market. The most pitiable feature is that use of these drugs are regularly causing long term implication for our physical health. Some of the common ones that are easily available and people use frequently without doctor's prescription are D-cold, Nimesulide and Analgin. These are use as pain killer but latest research shows that long term use of such medicines can affect human health in various ways by damaging liver, causing irregular heartbeats, depression, blood pressure fluctuations etc. This is the prime reason that most of European countries have disqualified and banned the manufacturing and consumption of these drugs. It has been recently pointed out that Indian drug regulatory authorities have refused to ban sale of 11 drug, including Furazolidone, Phenypropanolamine, Cisapride and Nimuselide, apart from over 80 drug combinations that are prohibited in other countries IPA have made various regulation and guideline for the control of these drug, but still they are in use because of lack of awareness in people.

Keywords: Banned Drugs,regulatory agency, pharmacovigilance, Drugs & Cosmetics act 1940

INTRODUCTION

Drugs undergo rigorous testing before they are introduced into the market. They are first tested in animals and then in human beings during clinical trials. The efficacy as well as safety profiles of the drug are tested. In spite of this, some adverse effects of drugs appear only after the drug is used in the general population. These adverse effects are detected though a process of regular monitoring after the drug is released called pharmacovigilance. If the adverse effects 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.[6]

Many spurious drugs that have been banned, withdrawn or marketed under restrictions in other countries, continue to be sold in India. The pharmaceutical companies and defaulters are playing with the lives of thousands of people

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who are not aware of the harmful effects of the drugs they sell.[2]

"More than 60,000 branded formulations are available in India. These preparations contain either single drug or drugs in fixed dose combination (FDC). All formulations are used for treatment or prevention of diseases. Out of it only few drugs are lifesaving and essential drugs, otherwise maximum of them are available as alternative or substitute to each other."

The safety of the combination drugs has to be thoroughly evaluated and there are considerations for the drugs that are already in the market as individual or single drug entity. However, the safety profile of the established drugs will alter when they are combined together. The total number of essential drugs mentioned in the 14th list of essential medicines by WHO is 312, out of which only 18 are fixed dose combinations. But many of the irrational combinations are popular and widely prescribed by physicians in our country.

Why, ban drug are available?

India has become a dumping ground for banned drugs. The business for production of banned drugs is blooming and because there are more consumers here and all illegalities are duly obeyed. The irony is that very few people know about the banned drugs and consume them unaware, causing a lot of damage to themselves. The issue is severe and we must not delay in spreading the warning message to the offenders and innocent people.[1]

As big time business enterprises and small time defaulters, pharmaceuticals have been growing in every direction. There are few provisions for a proper check and control of spurious drugs in Indian markets. Worst than that is the little knowledge and slapdash attitude of the buyers. Even at this time, a large population takes medicine and drugs without prescribing a doctor, which in fact is a very wrong decision and can be dangerous.[1]

Thanks to a virtually "absent" adverse drug reaction mechanism in the country, drugs like Analgin, Cisapride, Nimesulide and Piperazine, discarded worldwide due to serious side effects are among the bestsellers in India. According to a report of the World Health Organization, there has not been a single instance of adverse drug reaction reported against any drug in the country. The business of production of these discarded drugs is booming in India. Some of the most common ones include Nise (Dr Reddy's), Nimulid (Panacea Biotech) that are discarded for reported liver damage, while Vicks Action 500 from the stable of Procter and Gamble is discarded for increasing chances of brain hemorrhage. Anti-depressant drug Droperol (produced by Triokka) has been discarded for irregular heartbeats in patients. Anti-diarrhoeal drug Furoxone (from the house of Glaxo) was withdrawn from the market after reports of cancer in some patients, who were administered the drug. Eleven drugs - including cisapride, furazolidone, nimesulide and phenylpropanolamine - that have been banned, withdrawn or marketed under restrictions in North America, Europe and many Asian countries, continues to be sold in India.[1]

India's contribution to the worldwide collection of data on the side effects of different drugs is dismal. Countries like Ireland, Switzerland and Italy with a population of about 4 million, 33 million

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and 57 million, respectively had submitted 25, 33 and 225 adverse drug reaction on nimesulide. However, India, with over 1 billion population did not report any. Another drug Sildenafil (erectile dysfunction drug) had 18 adverse drug reactions reported from Australia but none from India. According to a health ministry source, monitoring of adverse drug reaction is not followed in the curriculum for medical students in India and majority of doctors do not maintain records on patients.[2]

New Delhi: A report by a parliamentary committee has shown that the drug industry regulator, the Drug Controller General of India (DCGI), has been approving, on average, one new drug a month without conducting mandatory clinical trials or seeking expert medical opinion—findings that expose the deep flaws prevalent in India's drug approval process.

The committee found that an "overwhelming" majority of the drugs were being approved on the basis of personal prescriptions and without any scientific evidence. The report concludes that "there is adequate documentary evidence to show that (expert) opinions are written by the invisible hands of drug manufacturers and experts merely oblige by putting their signatures".

Of the 42 drugs scrutinized, 11 were approved without phase-III clinical trials for safety and efficacy being conducted.

According to the committee's findings, CDSCO approved 33 new drugs (including Cipla Ltd's colistimethate and pirfenidone, Novartis Pharmaceutical's aliskiren and GlaxoSmithKline's ambrisentan) between January 2008 and October 2010 without conducting clinical trials and 25 drugs without seeking the opinion of medically-qualified experts.

It also found that four drugs (Novartis's everolimus, UCB Biosciences Inc.'s buclizine, Eli Lilly and Co.'s pemetrixid, and a fixed-dose combination of Theon Pharmaceuticals's pregabalin) were approved by "non-medical staff of CDSCO" without the mandatory clinical trials or opinion of medical experts and that 13 drugs were actually banned in developed countries.[1]

LIST OF DRUGS BANNED IN INDIA

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 oral preparations.
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

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21. Nimesulide formulations in children below the age of 12 years.
22. Cisapride
23. Rimonabant
24. Phenyl Propanolamine
25. Human Placenta Extract in topical application for wound healing and injection for pelvic
inflammatory diseases.
26. Sibutramine
27. R-Sibutramine
28. Gatifloxacin
29. Tegaserod

B. Fixed dose combination with any other drug

1. Corticosteroids with any other drug for internal use.
2. Chloramphenicol with any other drug for internal use.
3. Sodium bromide/chloral hydrates 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.
6. Metoclopramide with other drugs (except with aspirin/paracetamol).
7. Pectin and/or kaolin with any drug which is systematically absorbed from G.I. tract, except
for combination of pectin and/or kaolin with drugs not systematically absorbed.
8. Hydroxyquinolines with any other drug except in preparations for external use.
9. Oxyphenbutazone or phenylbutazone with any other drug.
10. Dextropropoxyphene with any other drug except antispasmodics and/or NSAIDs.
11. 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 Tranquillizers.
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.
12. Sedatives/Hypnotics/Anxiolytics with Analgesic-antipyretics.
13. H2 receptor antagonists with Antacids (except those combinations approved by Drugs
Controller, India).
14. Anthelmintics (except Piperazine) with a Cathartic/Purgative.
15. Salbutamol (or any other bronchodilator) with centrally acting Antitussive and/or an
Antihistamine.
16. Centrally acting Antitussives with Antihistamines having atropine like activity in
expectorants.
17. Centrally acting Antitussive and/or Antihistamine in preparations for cough associated with
asthma.
18. Laxative and/or antispasmodic drugs in enzyme preparations.
19. Glycerophosphates and/or other phosphates and/or CNS stimulant in liquid oral tonics.

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20. Estrogen and Progestin (other than oral contraceptives) containing per tablet Estrogen more
than 50 ug ethinylestradiol (or equivalent) and progestin more than 3 mg of norethisterone
acetate (or equivalent) and, all fixed dose combination injectable preparations containing
synthetic estrogen and progesterone.
21. Ethambutol with Isoniazid, except in the following daily doses:
Isoniazid 200 mg + Ethambutol 600 mg or
Isoniaizid 300 mg + Ethambutol 800 mg
22. 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

23. Essential oils with Alcohol having percentage higher than 20% proof (except preparations
given in the I.P.).
24. Liquid oral tonic preparations containing alcohol more than 20% proof.
25. Streptomycin with penicillin in parenteral preparation.
26. Antidiarrhoeals containing adsorbants like kaolin, pectin, attapulgite, activated charcoal etc.
27. Antidiarrhoeals containing phthalylsulfathiazole, succinyl sulfathiazole, sulfaguanidine,
neomycin, streptomycin, dihydrostreptomycin.
28. Antidiarrhoeal formulations for pediatric use containing diphenoxylate, loperamide, atropine,
hyoscyamine, halogenated hydroxyquionolines.
29. Antidiarrhoeals with electrolytes.
30. Fixed dose combinations of haemoglobin in any form.
31. Pancreatine or pancrelipase containing amylase, protease and lipase with any other enzyme.
32. Oral rehydration salts other than those conforming to the following parameters:
a) Oral rehydration salts on reconstitution to one litre shall contain: sodium-50 to 90 mM;
total osmolarity-240 to 290 mOsm; dextrose: sodium molar ratio-not less than 1:1 and not
more than 3:1.
b) Cereal based ORS on reconstitution to one litre shall contain: total osmolarity not more
than 2900 mOsm. Precooked rice equivalent to not less than 50 g and not more than 80 g
as total replacement of dextrose.
c) ORS may contain amino acids in addition to ORS conforming to the parameters
specified above and labeled with the indication for "Adult Choleratic Diarrhoea" only.
d) ORS shall not contain mono or polysaccharides or saccharin sweetening agent.
33. A drug, standards of which are prescribed in the 2nd schedule to Drugs and Cosmetics Act
with an Ayurvedic Siddha or Unani drug.
34. Vitamin B1, Vit B6 and Vit B12 for human use.
35. Diazepam with diphenhydramine HCl.
36. Nitrofurantoin with Trimethoprim.

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37. Phenobarbitone with any antiasthmatic drug, or with hyoscine and/or Hyoscyamine, or ergotamine and/or belladonna.
38. Haloperidol with any anticholinergic agent including propantheline Br.
39. Nalidixic acid with any antiamoebic including metronidazole.
40. Loperamide with furazolidone.
41. Cyproheptadine with lysine or peptone.
42. Diazepam and Diphenhyhydramine Hydrochloride.

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

Drugs Prohibited from the date of Notification

- Amidopyrine.
- Fixed dose combinations of vitamins with anti–inflammatory agents and tranquilizers.
- Fixed dose combinations of Atropine in Analgesics and Antipyretics.
- Fixed dose combinations of Strychnine and Caffeine in tonics.
- Fixed dose combinations of Yohimbine and Strychnine with Testosterone and Vitamins.
- Fixed dose combinations of Iron with Strychnine, Arsenic and Yohimbine.
- Fixed dose combinations of Sodium Bromide/chloral hydrate with other drugs.
- Phenacetin.
- Fixed dose combinations of antihistaminic with anti-diarrhoeals.
- Fixed dose combinations of Penicillin with Sulphonamides.
- Fixed dose combinations of Vitamins with Analgesics.
- Fixed dose combinations of any other Tetracycline with Vitamin C.
- Fixed dose combinations of Hydroxyquinoline group of drugs with any other drug except for preparations meant for external use.
- Fixed dose combinations of Corticosteroids with any other drug for internal use.
- Fixed dose combinations of Chloramphenicol with any other drug for internal use.
- Fixed dose combinations of crude Ergot preparations except those containing Ergotamine, Caffeine, analgesics, antihistamines for the treatment of migraine, headaches.
- Fixed dose combinations of Vitamins with Anti TB drugs except combination of Isoniazid with Pyridoxine Hydrochloride (Vitamin B6).
- Penicillin skin/eye Ointment.
- Tetracycline Liquid Oral preparations.
- Nialamide.
- Practolol.
- Methapyrilene, its salts.
- Methaqualone.
- Oxytetracycline Liquid Oral preparations.
- Demeclocycline Liquid Oral preparations.
- Combination of anabolic Steroids with other drugs.

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- Fixed dose combination of Oestrogen and Progestin (other than oral contraceptive) containing per tablet estrogen content of more than 50 mcg (equivalent to Ethinyl Estradiol) and progestin content of more than 3 mg (equivalent to Norethisterone Acetate) and all fixed dose combination injectable preparations containing synthetic Oestrogen and Progesterone. (Subs. By Noti. No. 743 (E) dt 10-08-1989)
- Fixed dose combination of Sedatives/ hypnotics/anxiolytics with analgesics-antipyretics.
- Fixed dose combination of Rifanpicin, isoniazid and Pyrazinamide, except those which provide daily adult dose given below:

Drugs	Minimum	Maximum
Rifampicin	450 mg	600 mg
Isoniazid	300 mg	400 mg
Pyrazinamide	1000mg	1500 mg

- Fixed dose combination of Histamine H-2 receptor antagonists with antacids except for those combinations approved by Drugs Controller, India.
- The patent and proprietary medicines of fixed dose combinations of essential oils with alcohol having percentage higher than 20% proof except preparations given in the Indian Pharmacopoeia.
- All Pharmaceutical preparations containing Chloroform exceeding 0.5% w/w or v/v whichever is appropriate.
- Fixed dose combination of Ethambutol with INH other than the following: INH Ethambutol 200 mg. 600 mg. 300 mg. 800 mg.
- Fixed dose combination containing more than one antihistamine.
- Fixed dose combination of any anthelmintic with cathartic/purgative except for piperazine/Santonim.
- Fixed dose combination of Salbutamol or any other bronchodilator with centrally acting anti-tussive and/or antihistamine.
- Fixed dose combination of laxatives and/or anti-spasmodic drugs in enzyme preparations.
- Fixed dose combination of Metoclopramide with systemically absorbed drugs except fixed dose combination of metoclopramide with aspirin/paracetamol
- Fixed dose combination of centrally acting, antitussive with antihistamine, having high atropine like activity in expectorants.
- Preparations claiming to combat cough associated with asthma containing centrally acting antitussive and/ or an antihistamine.
- Liquid oral tonic preparations containing glycerophosphates and/or other phosphates and / or central nervous system stimulant and such preparations containing alcohol more than 20% proof.

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- Fixed dose combination containing Pectin and/or Kaolin with any drug which is systemically absorbed from GI tract except for combinations of Pectin and/or Kaolin with drugs not systemically absorbed.
- Chloral Hydrate as a drug.
- Dovers Powder I.P.
- Dover's Powder Tablets I.P.
- Antidiarrhoeal formulations containing Kaolin or Pectin or Attapulgite or Activated Charcoal.

- Antidiarrhoeal formulations containing Phthalyl Sulphathiazole or Sulphaguanidine or Succinyl Sulphathiazole

- Antidiarrhoeal formulations containing Neomycin or Streptomycin or Dihydrostreptomycin including their respective salts or esters.
- Liquid Oral antidiarrhoeals or any other dosage form for pediatric use containing Diphenoxylate Lorloperamide or Atropine or Belladona including their salts or esters or metabolites Hyoscyamine or their extracts or their alkaloids.
- Liquid Oral antidiarrhoeals or any other dosage form for pediatric use containing halogenated hydroxyquinolines.
- Fixed dose combination of antidiarrhoeals with electrolytes.
- Patent and Proprietary Oral Rehydration Salts other than those conforming to the
- Fixed dose combination of Oxyphenbutazone or Phenylbutazone with any other drug.
- Fixed dose combination of Analgin with any other drug.
- Fixed dose combination of dextropropoxyphene with any other drug other than anti-spasmodics and/or non-steriodal anti-inflammatory drugs (NSAIDS).
- Fixed dose combination of a drug, standards of which are prescribed in the Second Schedule to the said Act with an Ayurvedic, Siddha or Unani drug.
- Mepacrine Hydrochloride (Quinacrine and its salts) in any dosage form for use for female sterilization or contraception.
- Fenfluramine and Dexfenfluramine.
- Fixed dose combination of Diazepam and Diphenhydramine Hydrochlo
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List of Gazette Notification Published

- The Principal Notification GSR 578 (E) dt.23.7.83.
- Added b GSR 4(E) dated 31.01.1984
- Added b GSR 322(E) dated 03.05.1984\
- Amended by GSR 863(E) dated 22.11.1985
- Amended by GSR 743(E) dated 10.08.1989
- Amended by GSR 1057(E) dated 03.11.1988
- Added by GSR 999(E) dated 26.12.1990
- Added by GSR 69(E) dated 11.02.1991
- Added by GSR 304(E) dated 7.06.1990
- Added by GSR 444(E) dated 7.06.1992
- Added by GSR 111(E) dated 22.02.1994
- Added by GSR 731(E) dated 30.09.1994
- Added by GSR 848(E) dated 7.12.1994

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- Added by GSR 57(E) dated 7.02.1995
- Added by GSR 633(E) dated 13.09.1995
- Added by GSR 793(E) dated 13.03.1995
- Added by GSR 93(E) dated 25.05.1997
- Added by GSR 499(E) dated 14.08.1998
- Added by GSR 394(E) dated 19.05.1999
- Added by GSR 405(E) dated 3.06.1999
- Added by GSR 169(E) dated 12.03.2001

Drugs Prohibited for Manufacture, Sale and Distribution from Subsequent Date

Drugs Formulation	Effective date	Notification
1.Cosmetics Licensed as toothpaste/tooth powder containing tobacco.	With immediate effect	GSR 444(E) dt.30.4.92
2.Parenteal Preparations fixed dose combination of streptomycin with Pencillin	Jan 1,1998	GSR 93(E) dt.25.2.97
3.Fixed dose combination of Vitamin B1, Vitamin B6 and Vitamin B12 for human use	Jan 1,2001	GSR 702(E) dt.14.10.99
4.Fixed dose combination of haemoglobin in any form (natural or synthetic).	Sep 1,2000	GSR 814(E) dt.16.12.99
5.Fixed dose combination of Pancreatin or Pancrelipase containing amylase, protease and lipase with any other enzyme.	Sept. 1,2000	GSR 814(E) dt.16.12.99
6. Fixed dose combination of Nitrofurantoin and trimethoprim.	Jan 1,2002	GSR 170(E) dt.12.3.01
7.Fixed dose combination of Phenobarbitone with any anti-asthmatic drugs.	Jan 1,2002	GRS 170(E) dt.12.3.01
8.Fixed dose combination of Phenobarbitone with Hyoscin and/or Hyoscyamine	Jan 1,2002	GSR 170(E) dt.12.3.01
9.Fixed dose combination of Phenobarbitone with Ergotamine and/or Belladona	Jan 1,2002	GSR 170(E) dt.12.3.01
10.Fixed dose combination of Haloperidol with any anti-cholinergic agent including Propantheline Bromide.	Jan 1,2002	GSR 170(E) dt.12.3.01
11.Fixed dose combination of Nalidixic Acid with any anti-amoebic including Metronidazole.	Jan 1,2002	GSR 170(E) dt.12.3.01
12.Fixed dose combination of Loperamide Hydrochloride with Furazolidone	Jan 1,2002	GSR 170(E) dt.12.3.01
13.Fixed dose combination of Cyproheptadine with Lysine or Peptone.	Jan 1,2003	GSR 170(E) dt.12.3.01
14.Astemizole	Apr.1,2003	GSR 191(E) dt.5.3.03
15.Terfinadine	Apr.1,2003	GSR 191(E) dt.5.3.03
16.Fenformin	Oct.1,2003	GSR 780(E) dt.1.10.03
17.Rafecoxib	Dec 13,2004	GSR 810(E) dt. 13.12.04
18.Valdecoxib and it's formulation	July 25,2005	GSR 510(E) dt. 25.07.05

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REASON FOR BAN[5]

Generic name	Use	Reason for ban	Brand names(s)
1. Analgin	Pain-killer	Bone-marrow depression	Novalgin, Baralgan
2. Cisapride	Acidity, constipation	Irregular heart beat	Ciza, Syspride
3. Droperidol	Anti-depressant	Irregular heart beat	Droperol
4. Furazolidone	Anti-diarrhoeal	Cancer	Furoxone, Lomofen*
5. Nimesulide	Pain-killer, fever	Liver failure	Nise, Nimulid
6. Nitrofurazone	Anti-bacterial cream	Cancer	Furacin, Emfurazone
7. Phenolphthalein	Laxative	Cancer	Jetomisol-P*
8.Phenylpropanolamine	Cold & cough	Stroke	D'Cold*, Vicks Action 500*
9. Oxyphenbutazone	NSAID	Bone marrow depression	Sioril
10. Piperazine	Anti-worms	Nerve damage	Piperazine, Helmazan*
11. Quiniodochlor	Anti-diarrhoeal	Damage to sight	Enteroquinol

* Denotes it is a combination product Analgin, Furazolidone and Nitrofurazone are banned for use even in animals in the United States. Analgin is banned even in Nepal, Vietnam and Nigeria (Reference: MIMS INDIA, September, 2005)

Indian Regulations & Guidelines:

CDSCO	Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare, Government of India provides general information about drug regulatory requirements in India.
NPPA	Drugs (Price Control) Order 1995 and other orders enforced by National Pharmaceutical Pricing Authority (NPPA), Government of India. View the list of drugs under price control
D & C Act, 1940	The Drugs & Cosmetics Act, 1940 regulates the import, manufacture, distribution and sale of drugs in India.
Schedule M	Schedule M of the D&C Act specifies the general and specific requirements for factory premises and materials, plant and equipment and minimum recommended areas for basic installation for certain categories of drugs.
Schedule T	Schedule T of the D&C Act prescribes GMP specifications for manufacture of Ayurvedic, Siddha and Unani medicines.
Schedule Y	The clinical trials legislative requirements are guided by specifications of Schedule Y of The D&C Act.
GCP guidelines	The Ministry of Health, along with Drugs Controller General of India (DCGI) and Indian Council for Medical Research (ICMR) has come out with draft guidelines for research in human subjects. These GCP guidelines are essentially based on Declaration of Helsinki, WHO guidelines and ICH requirements for good clinical practice.
The Pharmacy Act,1948	The Pharmacy Act, 1948 is meant to regulate the profession of Pharmacy in India.
The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954	The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 provides to control the advertisements regarding drugs; it prohibits the advertising of remedies alleged to possess magic qualities.
The Narcotic Drugs and Psychotropic Substances Act, 1985	The Narcotic Drugs and Psychotropic Substances Act, 1985 is an act concerned with control and regulation of operations relating to Narcotic Drugs and Psychotropic Substances.

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Links to important international guidelines and regulatory bodies

WHO (Medicines)	WHO guidelines on medicines policy, intellectual property rights, financing & supply management, quality & safety, selection & rational use of medicines, technical co-operation and traditional medicines.
WHO sites	WHO guidelines on all areas relevant to health of people all over.
ICH	International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) guidelines defining quality, safety, efficacy & related aspects for developing and registering new medicinal products in Europe, Japan and the United States
OECD	Organization for Economic Collaboration and Development including 30 member countries covers economic and social issues in areas of health care.
EMEA	European Medicines Agency (EMEA), a decentralized body of the European Union headquartered in London, prescribes guidelines for inspections and general reporting and all aspects of human & veterinary medicines in the European Union.
US FDA	Regulations, guidelines, notifications, news and communications from US Food and Drug Administration.
TGA	Specifications regulating medicines, medical devices, blood, tissues & chemicals, issued by Therapeutic Goods Administration, the Australian regulatory body.
South Africa	The department of Health, South Africa.
WTO	News, resources, documents and publications of the World Trade Organization (WTO), the global international organization dealing with the rules of trade between nations.
Codex Alimentarius	Collection of international food standards and guidelines for processed, semi–processed and raw foods, adopted by the Codex Alimentarius Commission under the Joint FAO / WHO Food Standards Programme.
MHRA	News, warnings, information and publications of Medicines and Healthcare products Regulatory Agency (MHRA), responsible for ensuring efficacy and safety of medicines and medical devices in the UK.
http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/index_e.html)	Advisories, warnings, recalls, reports, publications, activities, legislations and guidelines from Health Canada, the Federal Department responsible for health related issues in Canada.
Thai FDA	Thai Food and Drug Administration laws and regulations with respect to drugs, food, cosmetics and narcotics.
HSA, Singapore	Health Sciences Authority (HSA), the regulatory body of Singapore.
DOH, Philippines	The Department of Health, Philippines.
Medsafe, New Zealand	Medsafe, New Zealand Medicines and Medical Devices Safety Authority.
NPCB, Malaysia	Regulatory information, news and publications of National Pharmaceutical Control Bureau, Malaysia.
DGMP, Belgium	Guidelines and useful information to ensure safety, efficacy and quality of medicines, issued by Directorate-General Medicinal Products, Belgium.
BfArM, Germany	Licensing and registration guidelines for medicinal products laid down by Federal Institute for Drugs and Medical Devices, Germany
SwissMedic	Swiss regulatory agency for therapeutic products.
MPA, Sweden	Regulatory and surveillance guidelines issued by Medical Products Agency, Sweden.
NAFDAC, Nigeria	News, regulations and guidelines issued by The National agency for Food Administration and Control (NAFDAC), Nigeria.

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REGULATIONS & GUIDELINES:

Process of banning drug in India is done by DTAB (Drug technical advisory board) which is the final authority on imposing a ban. Drug controller general of India notifies all state drug authorities and manufacturer about ban on the drug.[7]

At IPA we understand the problems faced by pharma professionals in accessing requisite information in order to comply with the regulatory requirements at home and in the regulated foreign markets. We've tried to simplify things for you by assembling the important Indian and international guidelines and regulations in this section. [7]

CONCLUSION:

Whenever a drug is banned by the Drug Controller of India, it should stop being available in the market. But there are times when a drug is banned yet continues to be sold for a few months till stock lasts. Chemists don't hesitate to sell those drugs at their shops as doctor are prescribing those medicines despite of their implication and side effect on the patient. In fact central drugs standard control organization run by government of India has not made any strict guideline over a list of drug that have been banned European union and USA. The demand is still there for these drugs

and that is why they are supplied. Doctors and patients who are used to prescribing and using the drug should realize that there are better and safe alternatives. There have been campaigns against various drugs. Noted doctors keep themselves informed of the harmful side-effects of these drugs and do not prescribe them". These problems can only overcome by joint effort of doctor, government, chemist, association and manufacturer.

Reference:

1. http://www.indianexpress.com/; "All eyes on banned drugs", 2011.
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