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BANNED DRUGS IN INDIA: A STUDY AND REVIEW ON BANNED DRUGS IN INDIA

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ABSTRACT

It may not be possible to have a disease-free world but we can aspire for solutions to relieve misery and make patient's life. The main aim is to ensure good quality of life of human beings. This can only be achieved with quality drugs with maximum therapeutic benefit and minimum side effects, available to all at affordable cost. A patient relies on his physician and prescriber for his treatment. Thus, it is the duty of the physician to meet the patient's requirements to their satisfaction. A drug is usually prescribed to a patient for its positive effect but may give rise to several adverse effects. Some of the common ones that are easily available and used frequently without doctor's prescription e.g phenyl propanolamine, analgen, cisapride and nimesulide among several others which are being sold as OTC (Over The Counter Drug) product in India as there is no regulatory guidelines for list of OTC product are not available till now. Coxibs were the widely prescribed drugs until the recent setback with rofecoxib, valdicoxib which was withdrawn from the market by the innovator due to increased risk of heart attacks and strokes observed with its long-term use. It is required to grasp an idea about the medicine which were banned from time to time under what circumstances.

KEYWORDS: Drugs, Banned drugs, OTC.

INTRODUCTION

A drug, broadly speaking, all medicine for internal & external use of human beings or animal and all substances intended to be use for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals including preparations applied on human body for the purpose of repelling insects like mosquitoes. Such substances other than food intended to affect the structure or any function of the human body or intended to be used as destruction of vermin or insects which cause disease in human or animals. All substances intended for use as components of a drug including empty gelatin capsules and such device intended internal or external use in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, as may be specified from time to time by the central govt. by notification in the official gazette, after consultation with the board. 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/mass 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.

REASON FOR BANNING A DRUG: A drug is introduced into the market for the benefit of consumers. FDA approves a drug only when its safety is proved. However, a safe drug need not be thoroughly harmless. Every drug comes with its own adverse effects. But only when the risk: benefit ratio is reasonably low that the drug is approved by FDA.

The Reasons For Banning A Drug Are

1. Unexpected Problems: The adverse effects of drugs introduced into the market are well known. Morbidity and mortality are more due to known

adverse effects rather than unknown adverse effects. Some adverse effects are rare and cannot be elicited by clinical trials which highlight the commonly encountered adverse effects. Severe drug-induced liver diseases are one of the leading causes of banning drugs but is very rare to the extent of 1:5,000 to 1:10,000 exposures or less, which is easily missed in clinical trials and drug is introduced in the market.

2. **Excess Toxicity:** A drug may show toxicity only after it is introduced in the market and not at the time of clinical trials. The best example would be Cerivastatin (Baycol) which caused severe rhabdomyolysis.
3. **Availability of Safer Options:** A drug with less adverse effects and greater or similar efficacy is preferred. Terfenadine introduced in 1985 was banned in 1998 due to its implications in causation of cardiac rhythm abnormalities. This was because fexofenadine introduced in 1997 had similar efficacy but no such adverse effects.
4. **Harmful Interactions:** Mibefradil and astemizole were introduced in the market with known dangerous interactions with 3-4 drugs each. Consequently. they showed dangerous interactions with other drugs.

They were withdrawn due to availability, of other safer alternatives.

5. **Irrational Use:** The safety of thalidomide in pregnant women was not established. Still this drug was used in pregnant women, causing foetal toxicity and children were born with phocomelia. It was clearly mentioned that bromfenac sodium (NSAID) should be used only for a short time as it elevates liver enzymes when used over a long period of time. However, it was used for prolonged time period and this resulted in many cases of liver failure.
6. Failure Of Other Risk Management Options

To highlight the risks associated with a particular drug FDA educates health care professionals through letters (Dear doctor letters) and labeling changes, sometimes new warnings which are placed in black box (black box warnings). Labels are attached specifically for patients mentioning adverse effects and how to detect/avoid them. Some drugs are placed in category of restricted distribution, wherein they are made available only in certain conditions.

4. REGULATIONS & GUIDELINES: Under 26(A) of Drugs and Cosmetics act 1940 & Rules 1945 drugs are banned in India under Ministry Of Health and Family Welfare. 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.

Indian Regulations and 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 1995and other orders enforced by National Pharmaceutical Pricing Authority (NPPA), Government of India. View the list of drugs under price control here-D & C Act, 1940 The Drugs & Cosmetics Act, 1940 regulates the import, manufacture, & Rules 1945 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.

5. LIST OF BANNED DRUGS IN INDIA

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

1. Amidopyrine.
2. Fixed dose combinations of vitamins with anti-inflammatory agents and tranquilizers.
3. Fixed dose combinations of Atropine in Analgesics and Antipyretics.
4. Fixed dose combinations of Strychnine and Caffeine in tonics.
5. Fixed dose combinations of Yohimbine and Strychnine with Testosterone and Vitamins.
6. Fixed dose combinations of Iron with Strychnine, Arsenic and Yohimbine.
7. Fixed dose combinations of Sodium Bromide/chloral hydrate with other drugs.
8. Phenacetin.
9. Fixed dose combinations of antihistaminic with antidiarrhoeals.
10. Fixed dose combinations of Penicillin with Sulphonamides.
11. Fixed dose combinations of Vitamins with Analgesics.
12. Fixed dose combinations of any other Tetracycline with Vitamin C.
13. Fixed dose combinations of Hydroxyquinoline group of drugs with any other drug except for preparations meant for external use.
14. Fixed dose combinations of Corticosteroids with any other drug for internal use except for preparations meant for meter dose inhalers and dry powder inhalers.
15. Fixed dose combinations of Chloramphenicol with any other drug for internal use.
16. Fixed dose combinations of crude Ergot preparations except those containing Ergotamine, Caffeine, analgesics, antihistamines for the treatment of migraine, headaches.

17. Fixed dose combinations of Vitamins with Anti TB drugs except combination of Isoniazid with Pyridoxine Hydrochloride (Vitamin B6).
18. Penicillin skin/eye Ointment
19. Tetracycline Liquid Oral preparations.
20. Nialamide.
21. Practolol.
22. Methapyrilene, its salts.
23. Methaqualone.
24. Oxytetracycline Liquid Oral preparations.
25. Demeclocycline Liquid Oral preparations.
26. Combination of anabolic Steroids with other drugs
27. Chloral Hydrate as a drug.
28. Dovers Powder I.P.
29. Dover's Powder Tablets I.P.
30. Fenfluramine
31. Dexfenfluramine.
32. Fixed dose combination of Diazepam and Diphenhydramine Hydrochloride
33. Cosmetics Licensed as toothpaste/tooth powder containing tobacco.
34. Parenteal Preparations fixed combination of streptomycin with Pencillin
35. Fixed dose combination of Vitamin B1Vitamin B6 and Vitamin B12 for human use
36. Fixed dose combination of Pancreatin or Pancrelipase containing amylase, protease and lipase with any other enzyme.
37. Fixed dose combination of Nitrofurantoin and trimethoprim. 38.Astemizole
38. Terfinadine
39. Phenformin
40. Rofecoxib and its formulations
41. Valdecoxib and its formulations
42. Diclofenac and its formulations (for animal use)
43. Rimonabant
44. Rosiglitazone
45. Nimesulide formulations for human use in children below 12 years of age. 47.Phenypropanolamine and its formulations for human use.
46. Sibutramine and its formulations for human use
47. R-Sibutramine and its formulations for human use.
48. "Gatifloxacin formulation for systemic use in human by any route including oral and injectable".
49. Tegaserod and its formulations
50. Letrozole for induction of ovulation in anovulatory infertility.
51. Human Placental Extract and its formulations for human use except its 1. Topical application for wound healing, and 2. Injection for pelvic inflammatory disease (substituted by G.S.R 418E dt.30.5.2011)
52. Ayurvedic drugs prohibited for manufacture and sale through gazette notification under section 33 EED of the Drugs & Cosmetics Act,1940(23 of 1940) by the Ministry of Health & family Welfare.

a. All Ayurvedic drugs licensed as toothpastes 30.4.1992 /tooth-powder containg tobacco. G.S.R 443(E)

5(a) DRUGS PROHIBITED FROM MANUFACTURE, SALE AND DISTRIBUTION FROM SUBSEQUENT DATE OF NOTIFICATION: A gazette notification by Ministry of Health and Family Welfare has banned 344 medicines of fixed drug combinations. The Health Ministry banned 344 fixed drug combinations through a gazette notification. The ban, which comes into effect immediately, follows recommendations of an expert committee formed to examine the efficacy of these drug combinations.

1. fixed dose combination of Aceclofenac + Paracetamol + Rabeprazole
2. fixed dose combination of Nimesulide + Diclofenac
3. fixed dose combination of Nimesulide + Cetirizine + Caffeine
4. fixed dose combination of Nimesulide + Tizanidine
5. fixed dose combination of Paracetamol + Cetirizine + Caffeine
6. fixed dose combination of Diclofenac + Tramadol + Chlorzoxazone
7. fixed dose combination of Dicyclomine + Paracetamol + Domperidone
8. fixed dose combination of Nimesulide + Paracetamol dispersible tablets
9. fixed dose combination of Paracetamol + Phenylephrine + Caffeine
10. fixed dose combination of Diclofenac + Tramadol + Paracetamol
11. fixed dose combination of Diclofenac + Paracetamol + Chlorzoxazone + Famotidine
12. fixed dose combination of Naproxen + Paracetamol
13. fixed dose combination of Nimesulide + Serratiopeptidase
14. fixed dose combination of Paracetamol + Diclofenac + Famotidine
15. fixed dose combination of Nimesulide + Pitofenone + Fenpiverinium + Benzyl Alcohol
16. fixed dose combination of Omeprazole + Paracetamol + Diclofenac
17. fixed dose combination of Nimesulide + Paracetamol injection
18. fixed dose combination of Tamsulosin + Diclofenac
19. fixed dose combination of Paracetamol + Phenylephrine + Chlorpheniramine + Dextromethorphan + Caffeine
20. fixed dose combination of Diclofenac + Zinc Carnosine
21. fixed dose combination of Diclofenac + Paracetamol + Chlorpheniramine Maleate + Magnesium Trisillicate
22. fixed dose combination of Paracetamol + Pseudoephedrine + Cetrizine
23. fixed dose combination of Phenylbutazone + Sodium Salicylate
24. fixed dose combination of Lornoxicam + Paracetamol + Trypsin
25. fixed dose combination of Paracetamol + Mefenamic Acid + Ranitidine + Dicyclomine

26. fixed dose combination of Nimesulide + Dicyclomine
27. fixed dose combination of Heparin + Diclofenac
28. fixed dose combination of Glucosamine + Methyl Sulfonyl Methane + Vitamin D3 + Manganese + Boron + Copper + Zinc
29. fixed dose combination of Paracetamol + Tapentadol
30. fixed dose combination of Tranexamic Acid + Proanthocyanidin
31. fixed dose combination of Benzoxonium Chloride + Lidocaine
32. fixed dose combination of Lornoxicam + Paracetamol + Tramadol
33. fixed dose combination of Lornoxicam + Paracetamol + Serratiopeptidase
34. fixed dose combination of Diclofenac + Paracetamol + Magnesium Trisilicate
35. fixed dose combination of Paracetamol + Domperidone + Caffeine
36. fixed dose combination of Ammonium Chloride + Sodium Citrate + Chlorpheniramine Maleate + Menthol
37. fixed dose combination of Paracetamol + Prochlorperazine Maleate
38. Combikit of 3 tablets of Serratiopeptidase (enteric coated 20000 units) + Diclofenac Potassium & 2 tablets of Doxycycline
39. fixed dose combination of Nimesulide + Paracetamol Suspension
40. fixed dose combination of Aceclofenac + Paracetamol + Famotidine
41. fixed dose combination of Aceclofenac + Zinc Carnosine
42. fixed dose combination of Paracetamol + Disodium Hydrogen Citrate + Caffeine
43. fixed dose combination of Paracetamol + DL Methionine
44. fixed dose combination of Disodium Hydrogen Citrate + Paracetamol
45. fixed dose combination of Paracetamol + Caffeine + Codeine
46. fixed dose combination of Aceclofenac (SR) + Paracetamol
47. fixed dose combination of Diclofenac + Paracetamol injection
48. fixed dose combination of Azithromycin + Cefixime
49. fixed dose combination of Amoxicillin + Dicloxacillin
50. fixed dose combination of Amoxicillin 250 mg + Potassium Clavulanate Diluted 62.5 mg
51. fixed dose combination of Azithromycin + Levofloxacin
52. fixed dose combination of Cefixime + Linezolid
53. fixed dose combination of Amoxicillin + Cefixime + Potassium Clavulanic Acid
54. fixed dose combination of Ofloxacin + Nitazoxanide
55. fixed dose combination of Cefpodoxime Proxetil + Levofloxacin
56. Combikit of Azithromycin, Secnidazole and Fluconazole
57. fixed dose combination of Levofloxacin + Ornidazole + Alpha Tocopherol Acetate
58. fixed dose combination of Nimorazole + Ofloxacin
59. fixed dose combination of Azithromycin + Ofloxacin
60. fixed dose combination of Amoxycillin + Tinidazole
61. fixed dose combination of Doxycycline + Serratiopeptidase
62. fixed dose combination of Cefixime + Levofloxacin
63. fixed dose combination of Ofloxacin + Metronidazole + Zinc Acetate
64. fixed dose combination of Diphenoxylate + Atropine + Furazolidone
65. Combikit of Fluconazole Tablet, Azithromycin Tablet and Ornidazole Tablets
66. fixed dose combination of Ciprofloxacin + Phenazopyridine
67. fixed dose combination of Amoxycillin + Dicloxacillin + Serratiopeptidase
68. Combikit of Fluconazole Tablet, Azithromycin Tablet and Ornidazole Tablets
69. fixed dose combination of Ciprofloxacin + Phenazopyridine
70. fixed dose combination of Amoxycillin + Dicloxacillin + Serratiopeptidase
71. fixed dose combination of Azithromycin + Cefpodoxime
72. fixed dose combination of Lignocaine + Clotrimazole + Ofloxacin + Beclomethasone
73. fixed dose combination of Cefuroxime + Linezolid
74. fixed dose combination of Ofloxacin + Ornidazole + Zinc Bisglycinate
75. fixed dose combination of Metronidazole + Norfloxacin
76. fixed dose combination of Amoxicillin + Bromhexine
77. fixed dose combination of Ciprofloxacin + Fluticasone + Clotrimazole + Neomycin
78. fixed dose combination of Metronidazole + Tetracycline
79. fixed dose combination of Cephalexin + Neomycin + Prednisolone
80. fixed dose combination of Azithromycin + Ambroxol
81. fixed dose combination of Cilnidipine + Metoprolol Succinate + Metoprolol Tartrate
82. fixed dose combination of L-Arginine + Sildenafil
83. fixed dose combination of Atorvastatin + Vitamin D3 + Folic Acid + Vitamin B12 + Pyridoxine
84. fixed dose combination of Metformin + Atorvastatin
85. fixed dose combination of Clindamycin + Telmisartan

86. fixed dose combination of Olmesartan + Hydrochlorothiazide + Chlorthalidone
87. fixed dose combination of L-5-Methyltetrahydrofolate Calcium + Escitalopram i
88. fixed dose combination of Pholcodine + Promethazine
89. fixed dose combination of Paracetamol + Promethazine
90. fixed dose combination of Betahistine + Ginkgo Biloba Extract + Vinpocetine + Piracetam
91. fixed dose combination of Cetirizine + Diethyl Carbamazine
92. fixed dose combination of Doxylamine + Pyridoxine + Mefenamic Acid + Paracetamol
93. fixed dose combination of Drotaverine + Clidinium + Chlordiazepoxide
94. fixed dose combination of Imipramine + Diazepam
95. fixed dose combination of Flupentixol + Escitalopram
96. fixed dose combination of Paracetamol + Prochloperazine
97. fixed dose combination of Gabapentin + Mecobalamin + Pyridoxine + Thiamine
98. fixed dose combination of Imipramine + Chlordiazepoxide + Trifluoperazine + Trihexyphenidyl
99. fixed dose combination of Chlorpromazine + Trihexyphenidyl
100. fixed dose combination of Ursodeoxycholic Acid + Silymarin
101. fixed dose combination of Metformin 1000/1000/500/500mg + Pioglitazone 7.5/7.5/7.5/7.5mg + Glimepiride1/2/1/2mg
102. fixed dose combination of Gliclazide 80 mg + Metformin 325 mg
103. fixed dose combination of Voglibose+ Metformin + Chromium Picolinate
104. fixed dose combination of Pioglitazone 7.5/7.5mg + Metformin 500/1000mg
105. fixed dose combination of Glimepiride 1mg/2mg/3mg + Pioglitazone 15mg/15mg/15mg + Metformin 1000mg/
106. 1000mg/1000mg
107. fixed dose combination of Glimepiride 1mg/2mg+ Pioglitazone 15mg/15mg + Metformin 850mg/850mg
108. fixed dose combination of Metformin 850mg + Pioglitazone 7.5 mg + Glimepiride 2mg
109. fixed dose combination of Metformin 850mg + Pioglitazone 7.5 mg + Glimepiride 1mg
110. fixed dose combination of Metformin 500mg/500mg+Gliclazide SR 30mg/60mg + Pioglitazone 7.5mg/7.5mg
111. fixed dose combination of Voglibose + Pioglitazone + Metformin
112. fixed dose combination of Metformin + Bromocriptine
113. fixed dose combination of Metformin + Glimepiride + Methylcobalamin
114. fixed dose combination of Pioglitazone 30 mg + Metformin 500 mg
115. fixed dose combination of Glimepiride + Pioglitazone + Metformin
116. fixed dose combination of Glipizide 2.5mg + Metformin 400 mg
117. fixed dose combination of Pioglitazone 15mg + Metformin 850 mg
118. fixed dose combination of Metformin ER + Gliclazide MR + Voglibose
119. fixed dose combination of Chromium Polynicotinate + Metformin
120. fixed dose combination of Metformin + Gliclazide + Piogllitazone + Chromium Polynicotinate
121. fixed dose combination of Metformin + Gliclazide + Chromium Polynicotinate
122. fixed dose combination of Glibenclamide + Metformin (SR)+ Pioglitazone
123. fixed dose combination of Metformin (Sustainded Release) 500mg + Pioglitazone 15 mg + Glimepiride 3mg
124. fixed dose combination of Metformin (SR) 500mg + Pioglitazone 5mg
125. fixed dose combination of Chloramphenicol + Beclomethasone + Clomitrimazole + Lignocaine
126. fixed dose combination of Clotrimazole + Ofloxaxin + Lignocaine + Glycerine and Propylene Glycol
127. fixed dose combination of Chloramphennicol + Lignocaine + Betamethasone + Clotrimazole + Ofloxacin + Antipyrine
128. fixed dose combination of Ofloxacin + Clotrimazole + Betamethasone + Lignocaine
129. fixed dose combination of Gentamicin Sulphate + Clotrimazole + Betamethasone + Lignocaine
130. fixed dose combination of Clotrimazole + Beclomethasone + Ofloxacin + Lignocaine
131. fixed dose combination of Becloemthasone + Clotrimazole + Chloramphenicol + Gentamycin + Lignocaine Ear drops
132. fixed dose combination of Flunarizine + Paracetamole + Domperidone
133. fixed dose combination of Rabeprazole + Zinc Carnosine
134. fixed dose combination of Magaldrate + Famotidine + Simethicone
135. fixed dose combination of Cyproheptadine + Thiamine
136. fixed dose combination of Magaldrate + Ranitidine + Pancreatin + Domperidone
137. fixed dose combination of Ranitidine + Magaldrate + Simethicone
138. fixed dose combination of Magaldrate + Papain + Fungul Diastase + Simethicone
139. fixed dose combination of Rabeprazole + Zinc + Domperidone
140. fixed dose combination of Famotidine + Oxytacaine + Magaldrate
141. fixed dose combination of Ranitidine + Domperidone + Simethicone

142. fixed dose combination of Alginic Acid + Sodium Bicarbonate + Dried Aluminium Hydroxide + Magnesium Hydroxide
143. fixed dose combination of Clidinium + Paracetamol + Dicyclomine + Activated Dimethicone
144. fixed dose combination of Furazolidone + Metronidazole + Loperamide
145. fixed dose combination of Rabeprazole + Diclofenac + Paracetamol
146. fixed dose combination of Ranitidine + Magaldrate
147. fixed dose combination of Norfloxacin + Metronidazole + Zinc Acetate
148. fixed dose combination of Zinc Carnosine + Oxetacaine
149. fixed dose combination of Oxetacaine + Magaldrate + Famotidine

• Fixed dose combination of Rifampicin, 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

7. Updated list of drugs prohibited for import
1. Nialamide
2. Practotol
3. Amidopyrine
4. Phenaeetin
5. Methaqualone
6. Chloral hydrate as drug G.S.R 48(E) dt.31.1.84
7. Fenfluramine or Dexfenfluramine G.S.R 303(E) dt.07.06.91
8. Rimonabant G.S.R 884(E) dt.11.12.2009
9. F.D.C of Loperamide hydrochloride G.S.R 170(E) dt.12.3.01 With furazolidine
10. F.D.C of cyproheptane with G.S.R 170(E) dt.12.03.01 Lysine or peptone
11. Astemazole G.S.R 191(E) dt.05.03.03
12. Refecoxib G.S.R 810(E) dt.13.12.2004
13. Valdecoxin and its formulations. G.S.R 510(E) dt.25.07.2005
14. Diclofenac and its formulations G.S.R 499(E) dt.04.07.2008

Table 1: Some Drugs Banned In India Over The Last Decade with Reason.

Drug Name (Brandname, drug class)	Pharmacological category(use)	Manufacturer	Year of drug Release	Indian ban	Reason forwithdrawal
Astemizole (Hismanal, 2nd genantihistamine)	Astemizole (Hismanal, 2nd gen antihistamine)	Janssen Pharmaceutical	1997	2003	Rare but fatal QT interval prolongationand related arrhythmia ,cardio toxic effect
Cisapride (Propulsid, 5-HT4 agonist)	Gastroprokinetic (antiemetic)	Janssen Pharmaceutical	1980	2011	Rare but fatal QT interval prolongationand related arrhythmia.
Diclofenac	Analgesic	Novartis	1973	2008	Liver toxicity in vultures and hencebanned
Nimesulide(Nimed Nimedex,Nimesil,N imulid)	Analgesic (acute pain, osteoarthritis and primary dysmenorrhea)	Helsinn Healthcare (original developer), ByDr. Reddy's	1985	2011	liver toxicity and increased number ofreports of adverse drug reactions in children led to its withdrawal in India
Rofecoxib	Analgesic (osteoarthritis, acute pain, dysmenorrhoea)	Abbott Merck &Co	1999	2004	Increased risk ofheart attack andstroke on high doses.
Gatifloxacin(Tequin, 4th gen,fluoroquinolon e)	Antibacterial(respi ratory tract infection)	Bristol-MyersSquibb	1999	2011	Diabetes risk reported in a Canadian withdrawnfrom Indian market in 2011[11,14]
Terfinadine(Seldane)	Antihistaminicagent		1985	2002	Serious heartproblem
Letrozole (Femera, letroz)	infertility pill		1996	2011	Potential risks tobabies

9. Other items prohibited for manufacture, sale and distribution s. No.

Drugs Formulation Effective date Notification

1. Cosmetics Licensed as toothpaste/tooth powder containing tobacco.
2. With immediate effect GSR 444(E) dt.30.4.92
3. Parenteral Preparations fixed dose combination of streptomycin with Penicillin Jan 1,1998 GSR 93(E) dt.25.2.97
4. Fixed dose combination of Vitamin B1, Vitamin B6 and Vitamin B12 for human use Jan 1,2001 GSR 702(E) dt.14.10.99

5. Fixed dose combination of haemoglobin in any form (natural or synthetic). Sep 1,2000 GSR 814(E) dt.16.12.99.
6. 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
7. Fixed dose combination of Nitrofurantoin and trimethoprim. Jan 1,2002 GSR 170(E) dt.12.3.01
8. Fixed dose combination of Phenobarbitone with any anti- asthmatic drugs. Jan 1,2002 GRS 170(E) dt.12.3.01
9. Fixed dose combination of Phenobarbitone with Hyoscin and/or Hyoscyamine Jan 1,2002 GSR 170(E) dt.12.3.01.
10. Fixed dose combination of Phenobarbitone with Ergotamine and/or Belladona Jan 1,2002 GSR 170(E) dt.12.3.01.
11. Fixed dose combination of Haloperidol with any anti-cholinergic agent including Propantheline Bromide. Jan 1,2002 GSR 170(E) dt.12.3.01
12. Fixed dose combination of Nalidixic Acid with any anti-amoebic including Metronidazole. Jan 1,2002 GSR 170(E) dt.12.3.01.
13. Fixed dose combination Loperamide Hydrochloride Furazolidone of with Jan 1,2002 GSR 170(E) dt.12.3.01
14. Fixed dose combination of Jan 1,2003 GSR 170(E)
15. Cyproheptadine Peptone with Lysine or dt.12.3.01
16. Astemizole Apr.1,2003 GSR 191(E) dt.5.3.03
17. Terfinadine Apr.1,2003 GSR 191(E) dt.5.3.03
18. Fenformin Oct.1,2003 GSR 780(E) dt.1.10.03
19. Rofecoxib Dec 13,2004 GSR 810(E) dt. 13.12.04
20. Valdecoxib and it's formulation July 25,2005 GSR 510(E) dt. 25.07.05
21. Diclofenac and its formulations animal use for July 4, 2008 GSR 499(E) dt.4.07.08

Table 2: Drugs That Have Been Globally Discarded But Are Still Available In Indian Markets.

Drug name	Indication foruse	Reason for ban	Few available brands inmarket
Analgin	Analgesic	Bone marrowdepression	Novalgin, Baralgan M
Droperidol	Antidepressant	irregular heartbeat	Droperol
Furazolidone	antidiarrhoel	Cancer	Furoxone, lomofen
Nimusulide	NSAIDS	liver failure	Nise, Nimulid
Nitrofurazone	antibacterialcream	Cancer	Furacin, Megacin
Phenolphthalein	Laxative	Cancer	Agarol
Phenylpropanolamine	cough and cold	Stroke	D.Cold, Vicks Action 500
Oxyphenbutazone	NSAIDS	bone marrowdepression	Sioril
Piperazine	antiworms	Nerve Damage	Antipar
Quiniodochlor	Antidiarrheal	Damage to sight	Enteroquinol

National pharmacovigilance program of India: The national pharmacovigilance program (NPP) was established by the Ministry of Health and Family Welfare in New Delhi in 2010 as a means to gather ADR reports throughout the nation. The NPP comprises of a national coordinating center that receives ADR information from individual pharmacovigilance centers about the cause, source and the personnel involved in an adverse drug event via a vigiflow software interface operated by Uppsala Monitoring Center.The NPP has developed and expanded through fives phases of development since its initiation in 2010. In its initiation phase from 2010-2011, 40 medical schools were established as pharmacovigilance centers and personnel were trained in these pharmacovigilance centers.

Sub-committee to monitor banned drugs in India: Each country has its own organization that monitors its individual circulation of banned drugs. In India, prior to drug marketing, its safety and efficacy is ascertained in accordance with the Schedule Y of Drugs and Cosmetics Act. Even after market approval, the safety and efficacy of the drug is continuously examined on the basis of information gathered via Pharmocovigilance, Post-Marketing Surveillance and information reported from other countries. In order to examine such information, the Drugs Technical Advisory Board (DTAB) under Drugs and Cosmetics Act has constituted a sub-committee, consisting of experts on the subject who examine the information received from the sources mentioned above and take a final view as to whether to prohibit the manufacture, sale and distribution of drugs or to restrict its use and accordingly recommend the Government to make suitable amendments under Section 26 A of the Drugs and Cosmetics Act which empowers the Central Government to prohibit the manufacture, sale or distribution of such drug or cosmetics.

Conclusions: If all healthcare professional including physicians, nurses, pharmacist and others including the patient report all ADRs then regulatory authority can take action as soon as possible, and drugs which are banned worldwide may not also available in India too.

The importance of encouraging physicians, pharmacists, other health-care professionals, and patients to continue to report serious suspected adverse drug reactions, whether unknown or known, to manufacturers and their local regulatory agencies cannot be over emphasized. Drug development is becoming increasingly difficult. Continued attrition of potentially useful drugs because of serious unwanted effects will not help. Careful

premarketing screening should reduce the problem but may also reduce the number of potentially useful drugs available for full development and subsequent licensing. Better risk management strategies are needed to handle problems when they arise, by means other than revocation of licenses.

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