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# BANNED MEDICATIONS IN INDIA: AN ANALYSIS AND OVERVIEW OF PROHIBITED DRUGS IN INDIA

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**ABSTRACT**

While a disease-free world may be unattainable, we can strive to alleviate suffering and improve patients' lives. The primary goal is to ensure a high quality of life for individuals. This can only be accomplished with high-quality medications that offer maximum therapeutic benefits and minimal side effects, accessible to everyone at an affordable cost. Patients depend on their physicians and prescribers for proper treatment, making it the responsibility of the physician to meet the patient's needs satisfactorily. Drugs are typically prescribed for their beneficial effects but may cause various adverse effects. Common medications like phenylpropanolamine, analgen, cisapride, and nimesulide are frequently used without a doctor's prescription, sold as over-the-counter (OTC) products in India, where regulatory guidelines for OTC products are still lacking. Coxibs were widely prescribed until the recent issues with rofecoxib and valdecoxib, which were withdrawn from the market by the manufacturer due to an increased risk of heart attacks and strokes with long-term use. It is essential to understand the circumstances under which these medicines were banned over time.

**KEYWORDS:** Medications, Banned drugs, OTC.

## INTRODUCTION

A drug, in a broad sense, encompasses all medicines for internal and external use in humans or animals, as well as all substances intended for the diagnosis, treatment, mitigation, or prevention of any disease or disorder in humans or animals. This includes preparations applied to the human body to repel insects like mosquitoes. These substances, other than food, are intended to affect the structure or function of the human body or to be used for the destruction of vermin or insects that cause diseases in humans or animals. Additionally, all substances intended for use as components of a drug, including empty gelatin capsules and devices intended for internal or external use in the diagnosis, treatment, mitigation, or prevention of any disease or disorder in humans or animals, are regulated as specified by the central government through notifications in the official gazette, following consultation with the relevant board. Drugs undergo extensive testing before being introduced to the market. They are initially tested in animals and subsequently in humans during clinical trials to evaluate both efficacy and safety profiles. Despite this rigorous testing, some adverse effects of drugs become apparent only after the drug is used by the general population. These adverse effects are identified through a process of ongoing monitoring called pharmacovigilance. If the adverse effects are severe, the risks of using the drug outweigh the benefits, or the drug proves to be ineffective, the country may ban the drug, or the pharmaceutical company may voluntarily withdraw it. Some drugs may only cause adverse effects when combined with specific other drugs. In such instances, only the fixed-dose combination is banned, not the individual drugs. Numerous 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 to benefit consumers. The FDA approves a drug only when its safety is demonstrated. However, a safe drug need not be entirely harmless. Every drug comes with its own adverse effects. But only when the risk-benefit ratio is reasonably low is the drug approved by the 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 ones. Some

adverse effects are rare and cannot be detected 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 are very rare to the extent of 1:5,000 to 1:10,000 exposures or less, which is easily missed in clinical trials and the drug is introduced into the market.

2. **Excess Toxicity:** A drug may show toxicity only after it is introduced into the market and not during clinical trials. An example would be Cerivastatin (Baycol), which caused severe rhabdomyolysis.

3. **Availability of Safer Options:** A drug with fewer adverse effects and greater or similar efficacy is preferred. Terfenadine, introduced in 1985, was banned in 1998 due to its implications in causing 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 into the market with known dangerous interactions with 3-4 drugs each. Consequently, they showed dangerous interactions with other drugs. They were withdrawn due to the 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 fetal 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. However, it was used for a prolonged period, resulting in many cases of liver failure.

6. **Failure of Other Risk Management Options:** To highlight the risks associated with a particular drug, the FDA educates health care professionals through letters (Dear Doctor letters) and labeling changes, sometimes adding new warnings placed in a 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 the category of restricted distribution, wherein they are made available only under certain conditions.

**Regulations C Guidelines**

Under 26(A) of the Drugs and Cosmetics Act 1940 C Rules 1945, drugs are banned in India under the Ministry of Health and Family Welfare. The process of banning a drug in India is done by the DTAB (Drug Technical Advisory Board), which is the final authority on imposing a ban. The Drug Controller General of India notifies all state drug authorities and manufacturers about the ban on the drug.

**Indian Regulations and Guidelines**

- **CDSCO:** Central Drugs Standard Control Organization (CDSCO), Ministry of Health C Family Welfare, Government of India provides general information about drug regulatory requirements in India.
- **NPPA Drugs (Price Control) Order 1995:** Enforced by the National Pharmaceutical Pricing Authority (NPPA), Government of India. View the list of drugs under price control here.
- **DCC Act, 1940:** The Drugs C Cosmetics Act, 1940 regulates the import, manufacture, distribution, and sale of drugs in India.
- **Schedule M:** 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:** Prescribes GMP specifications for the manufacture of Ayurvedic, Siddha, and Unani medicines.
- **Schedule Y:** The clinical trials legislative requirements are guided by the specifications of Schedule Y of The DCC Act.

**List of Banned Drugs in India**

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 antihistamines with antidiarrheals.
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 metered 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, and antihistamines for the treatment of migraine and headache.
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.
39. Terfinadine.
40. Phenformin.
41. Rofecoxib and its formulations
42. Valdecoxib and its formulations.
43. Diclofenac and its formulations (for animal use).
44. Rimonabant.
45. Rosiglitazone.
46. Nimesulide formulations for human use in children below 12 years of age.
47. Phenypropanolamine and Its formulations for human use.
48. Sibutramine and its formulations for human use.
49. R-Sibutramine and its formulations for human use.
50. "Gatifloxacin formulation for systemic use in human by any route including oral and injectable".
51. Tegaserod and its formulations.
52. Letrozole for induction of ovulation in anovulatory Infertility.
53. 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).
54. Ayurvedic drugs prohibited for manufacture and sale through gazette notification under section 33 EED of the Drugs C Cosmetics Act, 1940(23 of 1940) by the Ministry of Health C family Welfare.

a. All Ayurvedic drugs licensed as toothpastes 30.4.1992 /tooth-powder containg tobacco. G.S.R 443€ 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 C 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/ 1000mg/1000mg
106. Fixed dose combination of Glimepiride 1mg/2mg+ Pioglitazone 15mg/15mg + Metformin 850mg/850mg
107. Fixed dose combination of Metformin 850mg + Pioglitazone 7.5 mg + Glimepiride 2mg
108. Fixed dose combination of Metformin 850mg + Pioglitazone 7.5 mg + Glimepiride 1mg
109. Fixed dose combination of Metformin 500mg/500mg+Gliclazide SR 30mg/60mg + Pioglitazone 7.5mg/7.5mg
110. Fixed dose combination of Voglibose + Pioglitazone + Metformin
111. Fixed dose combination of Metformin + Bromocriptine
112. Fixed dose combination of Metformin + Glimepiride + Methylcobalamin
113. Fixed dose combination of Pioglitazone 30 mg + Metformin 500 mg
114. Fixed dose combination of Glimepiride + Pioglitazone + Metformin
115. Fixed dose combination of Glipizide 2.5mg + Metformin 400 mg
116. Fixed dose combination of Pioglitazone 15mg + Metformin 850 mg
117. Fixed dose combination of Metformin ER + Gliclazide MR + Voglibose
118. Fixed dose combination of Chromium Polynicotinate + Metformin
119. Fixed dose combination of Metformin + Gliclazide + Piogllitazone + Chromium Polynicotinate
120. Fixed dose combination of Metformin + Gliclazide + Chromium Polynicotinate
121. Fixed dose combination of Glibenclamide + Metformin (SR)+ Pioglitazone
122. Fixed dose combination of Metformin (Sustainded Release) 500mg + Pioglitazone 15 mg + Glimepiride 3mg
123. Fixed dose combination of Metformin (SR) 500mg + Pioglitazone 5mg
124. Fixed dose combination of Chloramphenicol + Beclomethasone + Clomitrimazole + Lignocaine
125. Fixed dose combination of Clotrimazole + Ofloxaxin + Lignocaine + Glycerine and Propylene Glycol
126. Fixed dose combination of Chloramphennicol + Lignocaine + Betamethasone + Clotrimazole + Ofloxacin + Antipyrine
127. Fixed dose combination of Ofloxacin + Clotrimazole + Betamethasone + Lignocaine
128. Fixed dose combination of Gentamicin Sulphate + Clotrimazole + Betamethasone + Lignocaine
129. Fixed dose combination of Clotrimazole + Beclomethasone + Ofloxacin + Lignocaine
130. Fixed dose combination of Becloemthasone + Clotrimazole + Chloramphenicol + Gentamycin + Lignocaine Ear drops
131. Fixed dose combination of Flunarizine + Paracetamole + Domperidone
132. Fixed dose combination of Rabeprazole + Zinc Carnosine
133. Fixed dose combination of Magaldrate + Famotidine + Simethicone
134. Fixed dose combination of Cyproheptadine + Thiamine
135. Fixed dose combination of Magaldrate + Ranitidine + Pancreatin + Domperidone
136. Fixed dose combination of Ranitidine + Magaldrate + Simethicone
137. Fixed dose combination of Magaldrate + Papain + Fungul Diastase + Simethicone
138. Fixed dose combination of Rabeprazole + Zinc + Domperidone
139. Fixed dose combination of Famotidine + Oxytacaine + Magaldrate
140. fixed dose combination of Ranitidine+ domperidone
141. fixed dose combination of Alginic Acid + Sodium

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

**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€ dt.31.1.84
7. Fenfluramine or Dexfenfluramine G.S.R 303€ Dt.07.06.91
8. Rimonabant G.S.R 884€ dt.11.12.2009
9. F.D.C of Loperamide hydrochloride G.S.R 170€ Dt.12.3.01 With furazolidine
10. F.D.C of cyproheptane with G.S.R 170€ Dt.12.03.01 Lysine or peptone
11. Astemazole G.S.R 191€ dt.05.03.03
12. Refecoxib G.S.R 810€ dt.13.12.2004
13. Valdecoxin and its formulations. G.S.R 510€ Dt.25.07.2005
14. Diclofenac and its formulations G.S.R 499€ 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),
By Dr. 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 CCo 1999 2004 Increased risk of heart
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

**Drugs Formulation Effective Date Notification**

1. **Cosmetics Licensed as Toothpaste/Tooth Powder Containing Tobacco**
   - Effective immediately, GSR 444€ dated 30.4.92
2. **Parenteral Preparations with Fixed Dose Combination of Streptomycin and Penicillin**
   - Effective January 1, 1998, GSR 93€ dated 25.2.97
3. **Fixed Dose Combination of Vitamin B1, Vitamin

B6, and Vitamin B12 for Human Use**
- Effective January 1, 2001

4. **Fixed Dose Combination of Haemoglobin in Any Form (Natural or Synthetic)**
- Effective September 1, 2000, GSR 814€ dated 16.12.99
5. **Fixed Dose Combination of Pancreatin or Pancrelipase Containing Amylase, Protease, and Lipase with Any Other Enzyme**
- Effective September 1, 2000, GSR 814€ dated 16.12.99

6. **Fixed Dose Combination of Nitrofurantoin and Trimethoprim**
- Effective January 1, 2002, GSR 170€ dated 12.3.01

7. **Fixed Dose Combination of Phenobarbitone with Any Anti-Asthmatic Drugs**
- Effective January 1, 2002, GSR 170€ dated 12.3.01

8. **Fixed Dose Combination of Phenobarbitone with Hyoscin and/or Hyoscyamine**
- Effective January 1, 2002, GSR 170€ dated 12.3.01

9. **Fixed Dose Combination of Phenobarbitone with Ergotamine and/or Belladonna**
- Effective January 1, 2002, GSR 170€ dated 12.3.01

10. **Fixed Dose Combination of Haloperidol with Any Anti-Cholinergic Agent Including Propantheline Bromide**
- Effective January 1, 2002, GSR 170€ dated 12.3.01

11. **Fixed Dose Combination of Nalidixic Acid with Any Anti-Amoebic Including Metronidazole**
- Effective January 1, 2002, GSR 170€ dated 12.3.01

12. **Fixed Dose Combination of Loperamide Hydrochloride with Furazolidone**
- Effective January 1, 2002, GSR 170€ dated 12.3.01

13. **Fixed Dose Combination of Cyproheptadine with Peptone or Lysine**
- Effective January 1, 2003, GSR 170€ dated 12.3.01

14. **Astemizole**
- Effective April 1, 2003, GSR 191€ dated 5.3.03

15. **Terfinadine**
- Effective April 1, 2003, GSR 191€ dated 5.3.03
16. **Fenformin**
- Effective October 1, 2003, GSR 780€ dated 1.10.03

17. **Rofecoxib**
- Effective December 13, 2004, GSR 810€ dated 13.12.04

18. **Valdecoxib and Its Formulations**
- Effective July 25, 2005, GSR 510€ dated 25.07.05

19. **Diclofenac and Its Formulations for Animal Use**
- Effective July 4, 2008, GSR 499€ dated 4.07.08

**Drugs That Have Been Globally Discarded But Are Still Available in Indian Markets**

| **Drug Name** | **Indication for Use** | **Reason for Ban** | **Few Available Brands in Market** |
|---|---|---|---|
| Analgin | Analgesic | Bone marrow depression | Novalgin, Baralgan M |
| Droperidol | Antidepressant | Irregular heartbeat | Droperol |
| Furazolidone | Antidiarrheal | Cancer | Furoxone, Lomofen |
| Nimusulide | NSAIDS | Liver failure | Nise, Nimulid |
| Nitrofurazone | Antibacterial cream | Cancer | Furacin, Megacin |
| Phenolphthalein | Laxative | Cancer | Agarol |
| Phenylpropanolamine | Cough and cold | Stroke | D.Cold, Vicks Action 500 |
| Oxyphenbutazone | NSAIDS | Bone marrow depression | Sioril |
| Piperazine | Anti-worms | 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 to gather ADR (Adverse Drug Reaction) reports throughout the nation. The NPP consists of a national coordinating center that receives ADR information from individual pharmacovigilance centers via a Vigiflow software interface operated by the Uppsala Monitoring Center. The NPP has developed through five phases since its initiation in 2010. During the initial phase (2010-2011), 40 medical schools were established as pharmacovigilance centers and personnel were trained.

**Sub-Committee to Monitor Banned Drugs in India**

In India, prior to drug marketing, safety and efficacy are ascertained in accordance with Schedule Y of the Drugs and Cosmetics Act. Even after market approval, safety and efficacy are continuously examined via pharmacovigilance, post-marketing surveillance, and information reported from other countries. The Drugs Technical Advisory Board (DTAB) under the Drugs and Cosmetics Act has constituted a sub-committee of experts to examine this information and recommend whether to prohibit the manufacture, sale, and distribution of certain drugs or to restrict their use. Recommendations are made to the government to amend Section 26A of the Drugs and Cosmetics Act, empowering the central government to prohibit such activities.

## CONCLUSION

If all healthcare professionals, including physicians, nurses, pharmacists, and patients, report all ADRs, regulatory authorities can take action swiftly, potentially preventing globally banned drugs from being available in India. It is crucial to encourage the reporting of serious suspected adverse drug reactions to manufacturers and local regulatory agencies. Drug development is becoming increasingly challenging, and careful pre-marketing screening should reduce the problem but may also limit the number of potentially useful drugs available for full development and licensing. Better risk management strategies are needed to handle problems without resorting to revocation of licenses.

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