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# UNVEILING THE PROHIBITED: A REVIEW OF BANNED DRUGS IN INDIA

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**ABSTRACT:**

Striving to find ways to reduce suffering and improve patients' well-being is a noble endeavor, even if creating a disease-free world may be unachievable. The key aim is to provide effective medications that offer optimal therapeutic benefits with minimal side effects, ensuring they are affordable and accessible to everyone. Patients depend on healthcare providers to meet their needs efficiently. Doctors must prioritize patient satisfaction by prescribing medications that yield positive results while being cautious about potential adverse effects. In India, certain commonly used drugs like phenylpropanolamine, analgen, cisapride, and nimesulide are easily obtainable without a prescription due to the lack of regulatory oversight for (OTC)over-the-counter products. The usage of coxibs such as rofecoxib and valdecoxib, previously popular, declined due to safety concerns like the increased risk of heart attacks and strokes linked to prolonged use. It's crucial to comprehend the reasons behind the prohibition of specific medicines to protect patient well-being and safety.

**KEYWORD:**

Banned drug, Adverse effect, OTC, Toxicity, FDA, CDSCO.

**INTRODUCTION:**

Banned drugs are those drugs which are not allowed to intake because they cause various adverse effects more than the therapeutic effects. In general terms, a drug encompasses all medicines for both internal and external use in humans or animals, along with all substances intended for diagnosing, treating, easing, or preventing any illness in humans or animals, including products used on the body to repel insects such as mosquitoes. These substances, excluding food, are designed to impact the structure or function of the human body or to act as insecticides to combat pests or insects that spread diseases to humans or animals. All substances intended for use as part of a medication, including items like empty gelatin capsules and similar devices for internal or external use in diagnosing, treating, easing, or preventing diseases in humans or animals, are subject to specific regulations set by the central government through official notifications in the gazette after consulting with the board. Medications undergo rigorous testing before being introduced to the market. They undergo initial testing in animals and subsequently in humans during clinical trials to evaluate both their effectiveness and safety. Nonetheless, certain adverse effects of medications may only become apparent after widespread use in the general population. These adverse effects are identified through ongoing monitoring processes post-release, known as pharmacovigilance. If the side effects of a medication are severe, or if the risks of using the drug outweigh the benefits, or if the drug proves to be ineffective, the country may decide to ban the drug, or the pharmaceutical company may choose to voluntarily withdraw it from the market. Some medications may lead to adverse effects only when taken in combination with specific drugs. In such instances, only the fixed-dose combination is prohibited, not the individual drugs. Several individual drugs and fixed-dose combinations have been banned in India for manufacturing, marketing, and distribution purposes.

## 1) Reasons for a banning a drug:-

FDA makes sure a drug is safe before approving it. Even though a drug might be safe, it can still have some side effects. The FDA looks at whether the benefits of the drug are greater than the risks when deciding to approve it. This way, they ensure that the drug helps more than it harms, making it safe for people to use.

- **REASONS:-**

1. Serious side effects: One of the primary reasons for banning a drug is when it is discovered to have serious and harmful side effects that can endanger the health and well-being of individuals. These side effects could range from severe allergic reactions, organ damage, or other adverse effects that pose a significant risk to the users of the drug. In such cases, regulatory agencies and health authorities may decide to ban the drug to protect the public from potential harm.

2. Addiction potential: Another crucial reason for banning a drug is its high potential for addiction and abuse. Drugs that are highly addictive can lead to substance abuse disorders, dependence, and addiction, causing serious social, economic, and health problems. To prevent the misuse and harmful consequences associated with addiction, authorities may choose to ban such drugs to safeguard individuals and communities from the risks of addiction.

3. Ineffectiveness: Drugs that are found to be ineffective in treating the medical conditions they are intended for may be banned to ensure that patients receive appropriate and beneficial treatments. If a drug fails to provide the desired therapeutic outcomes or does not meet the necessary standards of efficacy, regulatory bodies may decide to ban its use to protect patients from ineffective treatments and promote the use of more efficient alternatives.
4. Availability of safer alternatives: When safer and more effective treatment options are available for a particular medical condition, authorities may opt to ban a drug that poses higher risks or has inferior efficacy. By restricting the use of less safe or less effective drugs, regulators aim to promote the adoption of better treatment options that offer improved outcomes while minimizing potential harm to patients.

5. Ethical concerns: Drugs that are derived from illegal sources, involve unethical practices in their production, or raise moral dilemmas may face bans due to ethical considerations. Regulatory bodies may prohibit the use of such drugs to uphold ethical standards in healthcare, ensure patient safety, and maintain the integrity of the pharmaceutical industry. By enforcing ethical guidelines, authorities aim to protect the rights and well-being of individuals and uphold the principles of ethical medical practice.

6. Environmental impact: Some drugs may be banned due to their adverse effects on the environment. Drugs that are not easily biodegradable or that contaminate water sources can have long-lasting negative impacts on ecosystems and wildlife. To prevent environmental harm, regulatory agencies may ban the production, use, or disposal of such drugs.

7. Regulatory violations: Drugs that fail to meet regulatory standards, such as quality control measures, manufacturing guidelines, or labeling requirements, may be subject to bans. Non-compliance with regulatory protocols can compromise the safety, efficacy, and quality of drugs, leading to their prohibition to ensure adherence to established regulations and standards.

8. Public safety concerns: In cases where a drug poses significant risks to public safety, such as being linked to accidents, violence, or criminal behavior, authorities may ban its use to protect the overall safety and well-being of society. Drugs that contribute to public health crises or societal disruptions may face bans to mitigate these risks and safeguard communities from harm.

- **RULES & GUIDELINES:-**

  in India, the Ministry of Health and Family Welfare can ban drugs under Section 26(A) of the Drugs and Cosmetics Act of 1940 and the Rules of 1945. The Drug Technical Advisory Board (DTAB) is responsible for the process of banning drugs and has the final say in imposing a ban. The Drug Controller General of India notifies all state drug authorities and manufacturers about the banned drug.

- **Indian Rules and guidelines:-**

In India, the rules and guidelines for banning drugs are outlined in the Drugs and Cosmetics Act of 1940 and the Rules of 1945 under Section 26(A). The Ministry of Health and Family Welfare has the authority to ban drugs through this process. The Drug Technical Advisory Board (DTAB) plays a crucial role in evaluating and recommending the banning of drugs, acting as the final authority on imposing a ban.The Drugs and Cosmetics Act classifies drugs into different schedules based on their potential for abuse and medical use. The schedules are as follows:

- **Schedule H:** Prescription drugs that should only be sold by prescription and dispensed under the supervision of a registered medical practitioner.
- **Schedule H1:** A subcategory of Schedule H that includes certain antibiotics and habit-forming drugs.
- **Schedule X:** Drugs that are considered to have a high potential for abuse and are subject to stricter regulations.

When a drug is banned in India, the Drug Controller General of India notifies all state drug authorities and manufacturers about the ban to ensure compliance with the regulatory measures. This notification process helps in preventing the distribution and sale of the banned drug in the country, safeguarding public health.

## LIST OF PROHIBITED MEDICATION:

### A. List Of Drugs Prohibitedp26a Of Drugs & Cosmetics Act 1940 By The Ministry Of Health And Family WelfareWelfare:

1. Amidopyrine.
2. Fixed dose combinations of Yohimbine and Strychnine with Testosterone and Vitamins.
3. Fixed dose combinations of Vitamins with Analgesics.
4. Fixed dose combinations of Atropine in Analgesics and Antipyretics.
5. Fixed dose combinations of Chloramphenicol with any other drug for internal use.
6. Fixed dose combination of Diazepam and Diphenhydramine Hydrochloride.
7. Fixed dose combinations of any other Tetracycline with Vitamin C.
8. Fixed dose combinations of Strychnine and Caffeine
9. Fixed dose combination of Pancreatin or Pancrelipase containing amylase, protease and lipase
10. Fixed dose combinations of Sodium Bromide/chloral hydrate with other drugs.
11. Fixed dose combinations of antihistaminic with antidiarrhoeals.
12. Fixed dose combination of Vitamin B1Vitamin B6 and Vitamin B12 for human use
13. Fixed dose combinations of Vitamins with Anti TB drugs except combination of Isoniazid with Pyridoxine Hydrochloride (Vitamin B6).
14. Penicillin skin/eye Ointment
15. Tetracycline Liquid Oral preparations.
16. Nialamide.
17. Methapyrilene, its salts.
18. Methaqualone.
19. Oxytetracycline Liquid Oral preparations.
20. Demeclocycline Liquid Oral preparations.
21. Combination of anabolic Steroids with other drugs
22. Fixed dose combinations of vitamins with anti-Inflammatory agents and tranquilizers.
23. Fixed dose combinations of Iron with Strychnine, Arsenic and Yohimbine.
24. Phenacetin.
25. Fixed dose combinations of Penicillin with Sulphonamides.
26. Fixed dose combinations of Hydroxyquinoline Group of drugs with any other drug except for Preparations meant for external use
27. Fixed dose combinations of Corticosteroids with any Other drug for internal use except for preparations meant for meter dose inhalers and dry powder inhalers.
28. Fixed dose combinations of crude Ergot preparations except those containing Ergotamine, Caffeine, analgesics, antihistamines for the treatment of migraine, headaches.
29. Nimesulide formulations for human use in children below 12 years of age.
30. Phenypropanolamine and its formulations for human use.

31.Sibutramine and its formulations for human use .

32."Gatifloxacin formulation for systemic use in human by any route including oral and injectable".

33. Tegaserod and its formulations

34. Fixed dose combination of Nitrofurantoin and Trimethoprim.

35. Terfinadine

36. Phenformin

37. Rofecoxib and its formulations

38. Letrozole for induction of ovulation in anovulatory infertility.

39. Valdecoxib and its formulations

40. Rimonabant

41. Rosiglitazone

42. Chloral Hydrate as a drug.

43. Dovers Powder I.P.

44. Dover's Powder Tablets I.P.

45. Fenfluramine

46. Astemizole

47. Dexfenfluramine.

48. Practolol

49.Diclofenac and its formulations (for animal use)

50. Cosmetics Licensed as toothpaste/tooth powder containing tobacco.

51. Parenteal Preparations fixed combination of Streptomycin with Pencillin

52. 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 418EDt.30.5.2011)

53. 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.

-All Ayurvedic drugs licensed as toothpastes 30.4.1992/tooth-powder containg tobacco. G.S.R 443€

**B. 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 Nimesulide + Pitofenone + Fenpiverinium + Benzyl Alcohol
2. fixed dose combination of Omeprazole + Paracetamol + Diclofenac
3. fixed dose combination of Nimesulide + Paracetamol injection
4. fixed dose combination of Tamsulosin + Diclofenac
5. fixed dose combination of Paracetamol + Phenylephrine + Chlorpheniramine + Dextromethorphanof + Caffeine
6. fixed dose combination of Diclofenac + Zinc Carnosine
7. fixed dose combination of Diclofenac + Paracetamol + Chlorpheniramine Maleate + Magnesium Trisillicate
8. fixed dose combination of Paracetamol + Pseudoephedrine + Cetrizine
9. fixed dose combination of Phenylbutazone + Sodium Salicylate
10. fixed dose combination of Lornoxicam + Paracetamol + Trypsin
11. fixed dose combination of Paracetamol + Mefenamic Acid + Ranitidine + Dicyclomine
12. fixed dose combination of Aceclofenac + Paracetamol + Famotidine
13. fixed dose combination of Aceclofenac + Zinc Carnosine
14. fixed dose combination of Paracetamol + Disodium Hydrogen Citrate + Caffeine
15. fixed dose combination of Paracetamol + DL Methionine
16. fixed dose combination of Disodium Hydrogen Citrate + Paracetamol
17. fixed dose combination of Paracetamol + Caffeine + Codeine
18. fixed dose combination of Aceclofenac (SR) + Paracetamol

19. fixed dose combination of Diclofenac + Paracetamol injection
20. fixed dose combination of Azithromycin + Cefixime
21. fixed dose combination of Amoxicillin + Dicloxacillin
22. fixed dose combination of Amoxicillin 250 mg + Potassium Clavulanate Diluted 62.5 mg
23. fixed dose combination of Azithromycin + Levofloxacin
24. fixed dose combination of Cefixime + Linezolid
25. fixed dose combination of Amoxicillin + Cefixime + Potassium Clavulanic Acid
26. fixed dose combination of Ofloxacin + Nitazoxanide
27. Fixed dose combination of Aceclofenac + Paracetamol + Rabeprazole
28. Fixed dose combination of Nimesulide + Diclofenac
29. Fixed dose combination of Nimesulide + Cetirizine + Caffeine
30. fixed dose combination of Nimesulide + Tizanidine
31. fixed dose combination of Paracetamol + Cetirizine + Caffeine
32. fixed dose combination of Diclofenac + Tramadol + Chlorzoxazone
33. fixed dose combination of Dicyclomine + Paracetamol + Domperidone
34. Fixed dose combination of Nimesulide + Paracetamol dispersible tablets
35. Fixed dose combination of Paracetamol + Phenylephrine + Caffeine
36. Fixed dose combination of Diclofenac + Tramadol + Paracetamol
37. Fixed dose combination of Diclofenac + Paracetamol + Chlorzoxazone + Famotidine
38. fixed dose combination of Naproxen + Paracetamol
39. fixed dose combination of Nimesulide + Serratiopeptidase
40. Fixed dose combination of Paracetamol + Diclofenac + Famotidine
41. fixed dose combination of Paracetamol + Domperidone + Caffeine
42. fixed dose combination of Ammonium Chloride + Sodium Citrate + Chlorpheniramine Maleate + Menthol
43. fixed dose combination of Paracetamol + Prochlorperazine Maleate
44. Combikit of 3 tablets of Serratiopeptidase (enteric Coated 20000 units) + Diclofenac Potassium & 2 Tablets of Doxycycline
45. fixed dose combination of Nimesulide + Paracetamol Suspension
46. fixed dose combination of Nimesulide + Dicyclomine
47. fixed dose combination of Heparin + Diclofenac
48. fixed dose combination of Glucosamine + Methyl Sulfonyl Methane + Vitamin D3 + Manganese + Boron + Copper + Zinc
49. fixed dose combination of Paracetamol + Tapentadol
50. fixed dose combination of Tranexamic Acid + Proanthocyanidin
51. fixed dose combination of Benzoxonium Chloride + Lidocaine
52. fixed dose combination of Lornoxicam + Paracetamol + Tramadol
53. fixed dose combination of Lornoxicam + Paracetamol + Serratiopeptidase
54. fixed dose combination of Diclofenac + Paracetamol + Magnesium Trisilicate
55. fixed dose combination of Oxetacaine + Magaldrate + Famotidine
56. fixed dose combination of Olmesartan + Hydrochlorothiazide + Chlorthalidone
57. fixed dose combination of L-5-Methyltetrahydrofolate Calcium + Escitalopram i
58. fixed dose combination of Pholcodine + Promethazine
59. fixed dose combination of Paracetamol + Promethazine
60. fixed dose combination of Betahistine + Ginkgo Biloba Extract + Vinpocetine + Piracetam
61. fixed dose combination of Cetirizine + Diethyl Carbamazine
62. fixed dose combination of Doxylamine + Pyridoxine + Mefenamic Acid + Paracetamol
63. fixed dose combination of Drotaverine + Clidinium + Chlordiazepoxide
64. fixed dose combination of Imipramine + Diazepam
65. fixed dose combination of Flupentixol + Escitalopram
66. fixed dose combination of Paracetamol + Prochloperazine
67. fixed dose combination of Gabapentin + Mecobalamin + Pyridoxine + Thiamine

68. fixed dose combination of Imipramine + Chlordiazepoxide + Trifluoperazine + Trihexyphenidyl
69. fixed dose combination of Chlorpromazine + Trihexyphenidyl
70. fixed dose combination of Ursodeoxycholic Acid + Silymarin
71. fixed dose combination of Metformin 1000/1000/500/500mg + Pioglitazone 7.5/7.5/7.5/7.5mg+ Glimepiride1/2/1/2mg
72. fixed dose combination of Gliclazide 80 mg + Metformin 325 mg
73. fixed dose combination of Voglibose+ Metformin + Chromium Picolinate
74. fixed dose combination of Pioglitazone 7.5/7.5mg + Metformin 500/1000mg
75. fixed dose combination of Glimepiride 1mg/2mg/3mg + Pioglitazone 15mg/15mg/15mg + Metformin 1000mg
76. fixed dose combination of Glimepiride 1mg/2mg+ Pioglitazone 15mg/15mg + Metformin 850mg/850mg
77. fixed dose combination of Metformin 850mg + Pioglitazone 7.5 mg + Glimepiride 2mg
78. fixed dose combination of Metformin 850mg + Pioglitazone 7.5 mg + Glimepiride 1mg
79. fixed dose combination of Metformin 500mg/500mg+Gliclazide SR 30mg/60mg + Pioglitazone 7.5mg/7.5mg
80. fixed dose combination of Voglibose + Pioglitazone + Metformin
81. fixed dose combination of Metformin + Bromocriptine
82. fixed dose combination of Cefpodoxime Proxetil + Levofloxacin
83. Combikit of Azithromycin, Secnidazole and Fluconazole
84. fixed dose combination of Levofloxacin + Ornidazole + Alpha Tocopherol Acetate
85. fixed dose combination of Nimorazole + Ofloxacin
86. fixed dose combination of Azithromycin + Ofloxacin
87. fixed dose combination of Amoxycillin + Tinidazole
88. fixed dose combination of Doxycycline + Serratiopeptidase
89. fixed dose combination of Cefixime + Levofloxacin
90. fixed dose combination of Ofloxacin + Metronidazole + Zinc Acetate
91. fixed dose combination of Diphenoxylate + Atropine + Furazolidone
92. Combikit of Fluconazole Tablet, Azithromycin Tablet and Ornidazole Tablets
93. fixed dose combination of Ciprofloxacin + Phenazopyridine
94. fixed dose combination of Amoxycillin + Dicloxacillin + Serratiopeptidase
95. Combikit of Fluconazole Tablet, Azithromycin Tablet and Ornidazole Tablets
96. fixed dose combination of Ciprofloxacin + Phenazopyridine
97. fixed dose combination of Amoxycillin + Dicloxacillin + Serratiopeptidase
98. fixed dose combination of Azithromycin + Cefpodoxime
99. fixed dose combination of Lignocaine + Clotrimazole + Ofloxacin + Beclomethason
100. fixed dose combination of Cefuroxime + Linezolid
101. fixed dose combination of Ofloxacin + Ornidazole + Zinc Bisglycinate
102. fixed dose combination of Metronidazole + Norfloxacin
103. fixed dose combination of Amoxicillin + Bromhexine
104. fixed dose combination of Ciprofloxacin + Fluticasone + Clotrimazole + Neomycin
105. fixed dose combination of Metronidazole + Tetracycline
106. fixed dose combination of Cephalexin + Neomycin + Prednisolone
107. fixed dose combination of Azithromycin + Ambroxol
108. fixed dose combination of Cilnidipine + Metoprolol Succinate + Metoprolol Tartrate
109. fixed dose combination of L-Arginine + Sildenafil
110. fixed dose combination of Atorvastatin + Vitamin D3 + Folic Acid + Vitamin B12 + Pyridoxine
111. fixed dose combination of Metformin + Atorvastatin
112. fixed dose combination of Clindamycin + Telmisartan
113. fixed dose combination of Metformin + Glimepiride + Methylcobalamin
114. fixed dose combination of Clotrimazole + Beclomethasone + Ofloxacin + Lignocaine
115. fixed dose combination of Becloemthasone + Clotrimazole + Chloramphenicol + Gentamycin+ Lignocaine Ear drops
116. fixed dose combination of Flunarizine + Paracetamole + Domperidone

117. fixed dose combination of Rabeprazole + Zinc Carnosine
118. fixed dose combination of Magaldrate + Famotidine + Simethicone
119. fixed dose combination of Cyproheptadine + Thiamine
120. fixed dose combination of Magaldrate + Ranitidine + Pancreatin + Domperidone
121. fixed dose combination of Ranitidine + Magaldrate + Simethicone
122. fixed dose combination of Magaldrate + Papain + Fungul Diastase + Simethicone
123. fixed dose combination of Rabeprazole + Zinc + Domperidone
124. fixed dose combination of Famotidine + Oxytacaine + Magaldrate
125. fixed dose combination of Ranitidine + Domperidone + Simethicone
126. fixed dose combination of Pioglitazone 30 mg + Metformin 500 mg
127. fixed dose combination of Glimepiride + Pioglitazone + Metformin
128. fixed dose combination of Glipizide 2.5mg + Metformin 400 mg
129. fixed dose combination of Pioglitazone 15mg + Metformin 850 mg
130. fixed dose combination of Metformin ER + Gliclazide MR + Voglibose
131. fixed dose combination of Chromium Polynicotinate + Metformin
132. fixed dose combination of Metformin + Gliclazide + Piogllitazone + Chromium Polynicotinate
133. fixed dose combination of Metformin + Gliclazide + Chromium Polynicotinate
134. fixed dose combination of Glibenclamide + Metformin (SR)+ Pioglitazone
135. fixed dose combination of Metformin (Sustainded Release) 500mg + Pioglitazone 15 mg + Glimepiride 3mg
136. fixed dose combination of Metformin (SR) 500mg + Pioglitazone 5mg
137. fixed dose combination of Chloramphenicol + Beclomethasone + Clomitrimazole +
138. Lignocaine
139. fixed dose combination of Clotrimazole + Ofloxaxin + Lignocaine + Glycerine and Propylene Glycol
140. fixed dose combination of Chloramphennicol + Lignocaine + Betamethasone + Clotrimazole + Ofloxacin + Antipyrine
141. fixed dose combination of Ofloxacin + Clotrimazole + Betamethasone + Lignocaine
142. fixed dose combination of Gentamicin Sulphate + Clotrimazole + Betamethasone + Lignocaine
143. fixed dose combination of Alginic Acid + Sodium Bicarbonate + Dried Aluminium Hydroxide+ Magnesium Hydroxide
144. fixed dose combination of Clidinium + Paracetamol + Dicyclomine + Activated Dimethicone
145. fixed dose combination of Furazolidone + Metronidazole + Loperamide
146. fixed dose combination of Rabeprazole + Diclofenac + Paracetamol
147. fixed dose combination of Ranitidine + Magaldrate
148. fixed dose combination of Norfloxacin + Metronidazole + Zinc Acetate
149. fixed dose combination of Zinc Carnosine + Oxetacaine

**C. 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. 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 No:1 :-**

**D. 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 |

- **Table No:2 :-**

**E. Some medications that got prohibited in India in the past some years along with the cause:-**

| Name of Medication (Class of drg, Brand of drug) | P'cological Group/use | Drug producer | Drug Release Year | Banned in India | Reason/cause for Banned |
|---|---|---|---|---|---|
| Gatifloxacin (4thgen,fluoro quinoloneTequin) | Antibacterial (respiratory tract infection) | Bristol-Myers Squibb | 1999 | 2011 | Diabetes risk Reported-in Canadian-withdrawnfrom Indian market in 2011[11,14] |
| Terfinadine (Seldane) | Antihistaminic agent | | 1985 | 2002 | Serious heart problem |
| Rofecoxib | Analgesic (osteoarthritis, acute-pain, dysmenorrhoea) | Abbott Merck &Co | 1999 | 2004 | Increased risk of heart attack andstroke on high doses. |
| Nimesulide(Nimed Nimedex,Nimesil, Nimulid) | Analgesic (acute pain, Osteoarthritis & primary dysmenorrhea) | Helsinn Healthcare (original developer) ByDr. Reddy's | 1985 | 2011 | liver toxicity &increased number of reports of adverse drug reactions in children led to its banned in India |
| Diclofenac | Analgesic | Novartis | 1973 | 2008 | Liver toxicity in vulture & hencebanned |
| Cisapride (5-HT4 agonist Propulsid | Gastroprokinetic (antiemetic) | Janssen P'ceutical | 1980 | 2011 | Rare but fatal QT interval Prolong ationand related arrhythmia. |
| Astemizole (2nd genantion histamine, Hismanal | Astemizole (Hismanal,2nd genantihistamine) | Janssen P'ceutical | 1997 | 2003 | Rare but fatal QT interval Prolongationand related arrhythmia,cardio toxic effect |

- **Table No:3:-**

**F. CDSCO "not of standard quality" (NSQ) Test: Full list of drugs that failed the CDSCO test :-**

| | Name of drugs | Manufacturer |
|---|---|---|
| 1. | Amoxicillin And Potassium Clavulanate Tablets IP (Clavam 625) | M/s. Alkem Health Science |
| 2. | Calcium And Vitamin D3 Tablets IP (Shelcal 500) | M/s. Pure & Cure Healthcare Pvt. Ltd. |
| 3. | Amoxicillin & Potassium Clavulanate Tablets (Mexclav 625) | M/s. Meg Lifesciences |
| 4. | Metformin Hydrochloride Sustained-release Tablets IP (Glycimet-SR-500) | M/s. Scott-Edil Pharmacia Ltd. |
| 5. | Vitamin B Complex with Vitamin C Softgels | M/s. Asoj Soft Caps Pvt. Ltd. |
| 6. | Rifmin 550 (Rifaximin Tablets 550 mg) | M/s. Legen Healthcare |
| 7. | Pantoprazole Gastro-Resistant and Domperidone Prolonged-Release Capsules IP (Pan – D) | M/s. Alkem Health Science |
| 8. | Paracetamol Tablets IP 500 mg | M/s.Karnataka-Antibiotics-and Pharmaceuticals Ltd. |
| 9. | Montair LC Kid (Montelukast Sodium & Levocetirizine Hydrochloride Dispersible Tablets) | M/s. Pure & Cure Healthcare Pvt. Ltd. |
| 10. | Compound Sodium Lactate Injection IP (Ringer Lactate Solution for Injection) (RL 500 ml) | M/s. Vision Parenteral Pvt. Ltd. |
| 11. | Fexofenadine Hydrochloride Tablets IP 120 mg | M/s. Maxtar Bio-Genics |
| 12. | Laxnorm Solution (Lactulose Solution USP) | M/s. Athens Life Sciences |
| 13. | Heparin Sodium Injection 5000 Units (Hostranil Injection) | M/s. Health Biotech Ltd. |
| 14. | Buflam Forte Suspension (Ibuprofen & Paracetamol Oral Suspension) | M/s. Ornate Pharma Pvt. Ltd. |
| 15. | Cepodem XP 50 Dry Suspension (Cefpodoxime Proxetil and Potassium Clavulanate Oral Suspension) | M/s. Hetero Labs Limited |

| | | |
|---|---|---|
| 16. | Nimesulide, Paracetamol and Chlorzoxazone Tablets (NICIP MR) | M/s. HSN International |
| 17. | Rolled Gauze (Non-Sterilized) | M/s. Blazon India |
| 18. | Ciprofloxacin Tablets IP 500 mg (Ocif-500) | M/s. Ornate Labs Pvt. Ltd. |
| 19. | Nimesulide,Phenylephrine Hydrochloride & Levocetirizine Dihydrochloride Tablets | M/s. Unispeed Pharmaceuticals Pvt. Ltd. |
| 20. | Adrenaline Injection IP Sterile 1 ml | M/s. Alves Healthcare Pvt. Ltd. |
| 21. | Compound Sodium Lactate Injection IP (Ringer Lactate Solution for Injection) RL 500ml | M/s. Vision Parentral Pvt. Ltd. |
| 22. | Vingel XL Pro Gel (Diclofenac Diethylamine, Linseed Oil, Methyl Salicylate, and Menthol Gel) | M/s. Universal Twin Labs |
| 23. | Atropine Sulphate Injection IP 2 ml | M/s. Nandani Medical Laboratories Pvt. Ltd. |
| 24. | Cefoperazone & Sulbactam For Injection (Todaycef 1.5 G) | M/s. Daxin Pharmaceuticals Pvt. Ltd. |
| 25. | Heparin Sodium Injection IP 25000 IU / 5ml | M/s. Scott-Edil Pharmacia Ltd. |
| 26. | Cefepime & Tazobactam for Injection (Crupime – TZ Kid Injection) | M/s. Cosmas Research Lab. Ltd. |
| 27. | Atropine Sulphate Injection IP (Atropine Sulphate) | M/s. Priya Pharmaceuticals |
| 28. | Salbutamol, Bromhexine HCI, Guaifenesin and Menthol Syrup (Acozil Expectorant) | M/s. Antila Lifesciences Pvt. Ltd. |
| 29. | Diclofenac Sodium IP | M/s. Sara Exports Ltd. |
| 30. | Escitalopram and Clonazepam Tablets IP (Klozaps-ES Tablets) | M/s. Digital Vision |
| 31. | Phenytoin Sodium Injection USP | M/s. Health Biotech Ltd. |
| 32. | Paracetamol, Phenylephrine Hydrochloride and Cetirizine Hydrochloride Suspension (Cethel Cold DS Suspension) | M/s. Win Cure Pharma |

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| 33. | Calcium 500 mg with Vitamin D3 250 IU Tablets IP | M/s. Life Max Cancer Laboratories |
| 34. | Amoxycillin and Potassium Clavulanate Tablets IP 625 mg (Renamega- CV 625) | M/s. Malik Lifesciences Pvt. Ltd. |
| 35. | Olmesartan Medoxomil Tablets IP 40 mg | M/s. Life Max Cancer Laboratories |
| 36. | INFUSION SET-NV | M/s. Medivision Healthcare |
| 37. | Telmisartan Tablets IP 40 mg | M/s. Life Max Cancer Laboratories |
| 38. | Alprazolam Tablets IP 0.25 mg (Erazol-0.25 Tablets) | M/s. Elikem Pharmaceuticals Pvt. Ltd. |
| 39. | Glimepiride Tablets IP (2 mg) | M/s. Mascot Health Series Pvt. Ltd |
| 40. | Calcium and Vitamin D3 Tablets IP | M/s. Unicure India Ltd |
| 41. | Metronidazole Tablets IP 400mg | M/s. Hindustan Antibiotics Ltd. |
| 42. | Paziva -40 | M/s. Gnosis Pharmaceuticals Pvt. Ltd. |
| 43. | Pantomed -40 | Digital Vision 176 |
| 44. | Cefixime Oral Suspension IP (Dry Syrup) | Nestor Pharmaceuticals Ltd. |
| 45. | Moxymed CV | Alexa Pharmaceuticals |
| 46. | Frusemide Injection IP 20 mg | Nestor Pharmaceuticals Ltd. |
| 47. | Kudajarishtam | Bala Herbals |
| 48. | Tab Nodosis | Steadfast Medishield Pvt. Ltd. |
| 49. | Haridrakhanda | Bhaskara Vilasam Vaidyasala |

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| 50. | Pantoprazole Inj. BP 40 mg | Kerala Medical Services Corporation Ltd. |
| 51. | Yogaraja Guggulu | Bhaskara Vilasam Vaidyasala |
| 52. | PANCEF-OF | Aglomed Ltd. |

- **How come banned drugs are still being sold in India:-**

India has become a hub for banned drugs, with only a minority aware of their consumption, leading to severe health issues like kidney and liver damage. Despite each country having its own list of prohibited drugs, it's worrying that certain medications banned elsewhere due to harmful effects are still easily accessible in the Indian market. Many painkillers, anti-diarrheal, and cough medicines banned internationally are commonly used in India due to factors like lack of awareness, poverty, self-medication, high costs, and poor communication between regulatory bodies(Drug Controller General of India (DCGI) and state drug regulators) . The Health Ministry of India has proposed removing drugs banned in multiple countries from the Indian market after thorough examination or taking necessary actions.

- **Awareness about Banned Drugs:-**

The use of drugs has become a fundamental part of medical practice. Despite government bans on certain drugs due to their harmful effects, these banned substances are still accessible, leading to potential harm to human health, including organ damage. To address this issue, it is crucial for government hospitals and private medical practitioners to conduct awareness campaigns to educate healthcare providers and the public about the current availability of drugs in the market, particularly focusing on internationally banned drugs and associated health risks. Establishing drug information centers to provide updated and unbiased drug information to healthcare providers and patients is essential. Educating medical students about banned and contentious drugs to discourage their future use is necessary. Pharmacists should actively engage in public information campaigns to educate consumers. Combating the use of banned drugs requires coordinated efforts from doctors, pharmacists, researchers, manufacturers, and the active involvement of strict regulatory authorities.

## CONCLUSIONS:

If all healthcare professionals, including doctors, nurses, pharmacists, and others, along with patients, report all adverse drug reactions (ADRs), the regulatory authority can promptly take action. This proactive approach can help prevent globally banned drugs from being available in India. It is crucial to stress the significance of encouraging physicians, pharmacists, healthcare professionals, and patients to report any serious suspected adverse drug reactions, whether known or unknown, to manufacturers and local regulatory agencies. The process of drug development is facing increasing challenges. The continual loss of potentially beneficial drugs due to severe side effects is detrimental. While thorough premarketing screening can mitigate this issue, it might also limit the number of promising drugs available for further development and eventual approval. Implementing improved risk management strategies is essential to address issues as they arise, beyond merely revoking licenses.

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