



Review Article

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Individual Drugs and the Reasons for Banning in India

Raga Deepika K*, Naresh Gorantla, Hindustan Abdul Ahad, Rajesh Pavan A

Balaji College of Pharmacy, Ananthapuramu, Andhra Pradesh, India

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Abstract

Drug development process is a robust process that can make and assure a drug with least possible side effects for human consumption. After a series of quality control process only a drug can be released into market. But some adverse effects of drugs appear only after the drug is used in general population. 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. But unfortunately many of general population and some doctors also don't know about those drugs and use them regularly which cause serious health effects. The government has to bring strict laws on manufactures not to produce such drugs and also it is the duty of the doctors not to prescribe such drugs so that the manufacturers will stop manufacturing of such dangerous drugs.

Keywords: Adverse effects, Quality control, ban.

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*Corresponding author

Raga Deepika K

Balaji College of Pharmacy,
Ananthapuramu, Andhra Pradesh, India
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1. Introduction

India has become a dumping ground for banned drugs; also the business for production of banned drugs is booming and many people don't know about these banned drugs and consume them causing a lot of damage to themselves. Doctors do not report side effects of any drug and the Drug Controller General of India (DCGI) is the sole authority to endorse the manufacture, sale and ban of a drug. Drug development process is a robust process that can make and assure a drug with least possible side effects for human consumption. After a series of quality control process only a drug can be released into market. But some adverse effects of drugs appear only after the drug is used in general population. 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. The present review gives information about the individual drugs that are banned in India with the reason of banning.

An Indian medical website stated that several drugs, which are banned for serious side effects in developed nations like US, Canada and Europe, are freely available in India. Though the list of such drugs is long, we have given

reasoning for some drugs. "Under the provisions of section 26A of the Drug and Cosmetic Act, the Drug Controller General of India (DCGI) and Ministry of Health and Welfare have the power to take the decision on private manufacturing, sale and ban of drugs in India," "The decision to ban and to manufacture is taken in consultation with the Drugs Technical Advisory Board." [1]

The List of Banned Drugs in India

The Government of India vide notifications published in the Gazette of India vide G.S.R. No. 578 (E) dated 23/07/1983 and subsequent amendments, made under Section 26 A of Drugs and Cosmetics Act, 1940 has prohibited the manufacture, sale and distribution of the following drugs which do not have any therapeutic justification or are likely to involve risk to human beings:

- a. Amidopyrine, an Antipyretic-analgesic is likely to cause agranulocytosis, their major adverse reaction. [2]
- b. Aminopyrine, an Antipyretic-analgesic induces Blood Dyscrasias, agranulocytosis, aplastic anaemia. [3-6]
- c. Analgin, acts as analgesic causes Bone marrow depression.
- d. Cisapride, a prokinetic agent that increases muscle contractions of lower oesophagus has proven to cause irregular heartbeat.
- e. Droperidol, an Anti-depressant also causes irregular heartbeat.
- f. Furazolidone, an Anti diarrhoeal has banned because of its carcinogenicity.
- g. Nimesulide, a new generation Analgesic and Antipyretic causes Liver failure.
- h. Nitrofurazone in cream formulation that can be used as an Antibacterial also proven to be carcinogenic in nature.
- i. Oxyphenbutazone, a Non-steroidal anti-inflammatory drug can cause Bone marrow depression.
- j. Phenacetin, an Antipyretic and Analgesic drug causes Nephropathy.
- k. Phenolphthalein, that can act as a laxative also proven to cause Cancer.
- l. Phenylpropanolamine, a Decongestant used to relieve cold and cough has banned because of the risk of heart stroke.
- m. Piperazine, an Anthelmintic that can be used against worms can cause Nerve damage. [7]
- n. Quiniodochlor, an Anti-diarrhoeal drug can cause damage to vision.[8]
- o. Penicillin in skin/eye Ointment formulation that can act as Antibiotic can cause skin lesions and Pruritis. [9,10]
- p. Tetracycline in Liquid Oral preparations is likely to cause Cardiovascular disturbances like Intracranial hypertension, pericarditis and metabolic disturbances like Brown/black discoloration of thyroid gland (no dysfunction reported), hypoglycemia.
- q. Nialamide, has banned due to interactions with food products containing tyrosine.
- r. Practolol, the beta-blocker used to treat high blood pressure and angina, as well as various heart conditions was found to cause an immune reaction known as oculomucocutaneous syndrome, causing inflammation of the eyes, mucous membrane and skin.[11]
- s. Melitracen, a tricyclic antidepressant used for a wide range of disorders such as psychogenic depression, depressive neuroses, masked depression, menopausal depression, dysphoria in alcoholics and drug addicts but causes risk in pregnant women.
- t. Extract of Human Placenta is banned as it can transmit diseases and pose serious health hazards to consumers and also 10-fold increased risk of heart attacks and stroke.
- u. Phenylpropanolamine used in the treatment of cough & cold has banned as its prolonged use leads to paralysis..
- v. Methaqualone that can act as Hypnotic and sedative by depressing CNS is highly addictive. People become physically dependent on it and have severe withdrawal symptoms in rehabilitation. Causes peripheral neuritis on prolonged administration.[12-14].
- w. Fixed Combination of Trimethoprim and Nitrofurantoin: Trimethoprim is active against *E. coli* and *Klebsiella*, while Nitrofurantoin is active chiefly against *E.coli* and *enterococci*. Trimethoprim can cause side-effects such as skin reactions, gastro-intestinal disturbances and bone marrow depression, while Nitrofurantoin use is associated with gastro-intestinal disturbances, peripheral neuropathy, hypersensitivity reactions and acute or chronic pulmonary reactions.
- x. Quiniodochlor, that can act as Anti-diarrhoeal can cause damage to sight.

The list of drugs banned with their brand names and reasons for their ban is shown in table 1.

Table 1: List of drugs banned.

| Generic name | Use | Reason for ban | Brand names(s) |
|--------------|-----------------------|------------------------|--------------------|
| Analgin | Pain-killer | Bone-marrow depression | Novalgin, Baralgin |
| Cisapride | Acidity, constipation | Irregular heart beat | Ciza, Syspride |
| Droperidol | Anti-depressant | Irregular heart beat | Droperol |
| Furazolidone | Anti-diarrhoeal | Cancer | Furoxone, |

| | | | |
|---------------------|----------------------|------------------------|--------------------------|
| Nimesulide | Pain-killer, fever | Liver failure | Nise, Nimulid |
| Nitrofurazone | Anti-bacterial cream | Cancer | Furacin, Emfurazone, |
| Phenylpropanolamine | Cold & cough | Stroke | D'Cold, Vicks Action 500 |
| Oxyphenbutazone | NSAID | Bone marrow depression | Sioril |
| Piperazine | Anti-worms | Nerve damage | Piperazine, Helmazan |
| Quiniodochlor | Anti-diarrhoeal | Damage to sight | Enteroquinol |

2. Conclusion

The Drug controller of India is the highest authority of India that approves or ban of any drug in India. If any drug is found to have serious harmful adverse effects the government may issue the ban order and all manufacturers and wholesalers are asked not to ask that particular drug. But unfortunately many of general population and some doctors also don't know about those drugs and use them regularly which cause serious health effects. The government has to bring strict laws on manufactures not to produce such drugs and also it is the duty of the doctors not to prescribe such drugs so that the manufacturers will stop manufacturing of such dangerous drugs.

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