Awareness About Banned Drug

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Abstract **- Pharmacovigilance is useful in assuring the safety of medicines and protecting the consumers from their harmful effects. A number of single drugs as well as fixed dose combinations have been banned from manufacturing, marketing and distribution in India. An important issue about the availability of banned drugs over the counter in India is that sufficient adverse drug reactions data about these drugs have not been reported. The most common categories of drugs withdrawn in the last decade were nonsteroidal anti-inflammatory drugs (28%), antidiabetics (14.28%), anti-obesity (14.28%), antihistamines (14.28%), gastroprokinetic drugs (7.14%), breast cancer and infertility drugs (7.14%), irritable bowel syndrome and constipation drugs (7.14%) and antibiotics (7.14%). Drug withdrawals from market were made mainly due to safety issues involving cardiovascular events (57.14%) and liver damage (14.28%). Majority of drugs have been banned in the past 3-5 years in other countries but are still available for sale in India. 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.**

INTRODUCTION

Drugs undergo rigorous testing before they are introduced into the market. They are first tested in animals and then in human beings during clinical trials. The efficacy as well as safety profiles of the drug are tested. In spite of this, some adverse effects of drugs appear only after the drug is used in the general population. Many spurious drugs that have been banned, withdrawn or marketed under restrictions in other countries, continue to be sold in India. The pharmaceutical companies and defaulters are playing with the lives of thousands of people who are not aware of the harmful effects of the drugs they sell.

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

MOST OF THE DRUGS BANNED IN OTHER COUNTRIES

BUT AVAILABLE IN INDIA

Oxyphenbutazon: Oxyphenbutazone, a metabolite of phenylbutazone, is an NSAID. It has been used for episceleritis, osteoarthritis, and rheumatoid arthritis etc. the severe adverse effects of oxyphenbutazone, which give rise to further complications include allergic reactions, abdominal pain, blurred vision.

Metamizole: Metamizole (Dipyrone) belongs to a group of drugs that eliminate pain and reduce fever. Metamizole can cause damage to the bone marrow (granulocytopenia, agranulocytosis, hemolytic anemia, aplastic anemia.), digestive disorders etc.

Cisapride: Cisapride is a "PROKINETIC AGENT" that used for treatment of gastroesophageal reflux disease GERD). There is no evidence it is effective for this use in children. evidence for its use in constipation

is not clear. It has been found to cause cardiac arrhythmias (irregular heart rhythms)

Nimesulide: Nimesulide is a non-steroidal anti-inflammatory drug, used for painful inflammatory conditions, back pain, dysmenorrheal, postoperative pain, osteoarthritis and fever. Caution should be exercised in patients with history of stomach problem, high blood pressure, fluid retention, abdominal discomfort, heartburn, abdominal cramps, nausea, vomiting and diarrhea, headache, dizziness and drowsiness, blood in urine and kidney failure.

Phenylpropanolamine: Phenylpropanolamine is a "PROKINETIC AGENT" that used for treatment of gastroesophageal reflux disease (GERD). But heart stroke and heart attack can cause due to adverse effect of phenylpropanolamine.

Fixed dose combinations (FDCs)

A combination of two or more actives in a fixed ratio of doses is known as fixed dose combination. It may be administered as single entity products given concurrently or as finished pharmaceutical product. The development of fixed-dose combinations (FDCs) is becoming increasingly important from a public health perspective. Such combinations of drugs are being used in the treatment of a wide range of conditions and are particularly useful in the management of HIV/AIDS, malaria and tuberculosis, which are considered to be the foremost infectious disease threats in the world today. FDCs have advantages when there is an identifiable patient population for whom treatment with a particular combination of actives in a fixed ratio of doses has been shown to be safe and effective and when all of the actives contribute to the overall therapeutic effect. In addition there can be real clinical benefits in the form of increased efficacy and/or a reduced incidence of adverse effects, but such claims should be supported by evidence. Additional advantages of FDCs are potentially lower costs of manufacturing compared to the costs of producing separate products administered concurrently, simpler logistics of distribution, improved patient adherence and reduced development of resistance in the case of antimicrobials. Importantly, as for any new medicine the risks and benefits should be defined and compared.

Banned and Approved Fixed dose combination drugs

An adverse drug reaction (ADR) as defined by World Health Organization (WHO) is a noxious, unintended effect of a drug, occurring at normal doses in humans for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function. The fixed dose combinations are banned due to they could artificially improve their performance and shows various adverse effects more than therapeutic effects. Whose production or use is prohibited or strictly controlled via prescription. Banned drugs are still available in India due to lack of awareness and law enforcement. The government of India needs to enforce laws and provide information to public and physicians about banned drugs, approved drugs and the reasons through drug information centers. The pharmacist should play an active role in patient education of drugs regularly and then play an important role on eliminating the market for banned drugs. On the basis of the recommendations of the Expert Committee appointed by the Central Government of India and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government of India prohibits/banned a total of 336 drug fixed dose combinations for the manufacturing, sale and distribution for human use with effect from 10th March, 2016.

LIST OF DRUGS BANNED IN INDIA

A. Single drug preparations (or combinations of)

1. Amidopyrine
2. Phenacetin
3. Nialamide
4. Methaqualone
5. Methapyrilene (and its salts)
6. Practolol
7. Penicillin skin/eye ointment
8. Tetracycline/Oxytetracycline/Demeclocycline liquid oral preparations.
9. Chloral hydrate
10. Dover's powder and Dover's powder tablets I.P.
11. Chloroform exceeding 0.5% w/w or v/v in pharmaceutical preparations.
12. Mepacrine HCl (Quinacrine and its salts) in any dosage form for use for female sterilization or contraception.
13. Fenfluramine
14. Dexfenfluramine
15. Terfenadine
16. Astemizole

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

REGULATIONS & GUIDELINES

Process of banning drug in India is done by DTAB (Drug technical advisory board) which is the final authority on imposing a ban. Drug controller general of India notifies all state drug authorities and manufacturer about ban on the drug. At IPA we understand the problems faced by pharma professionals in accessing requisite information in order to comply with the regulatory requirements at home and in the regulated foreign markets. We've tried to simplify things for you by assembling the important Indian and international guidelines and regulations in this section.

CONCLUSION

The government banned FDC drugs, extending to about 6,000 brands, on 10 March 2016, citing health risks, based on a report by a six-member committee headed by Chandrakant Kokate. The Kokate panel, which submitted its report on 20 January 2015, termed 963 FDCs irrational, posing health threats. According to industry estimates, the current ban is expected to impact the Rs.98,000 crore pharmaceutical industry in India by about Rs.3,800 crore a year. Pharma companies soon moved the high court. Pfizer was the first to be granted a stay on the ban of its cough syrup Corex. The high court said the government action appeared hasty and arbitrary. The pharmacist should play an active role in patient education of such banned and approved drugs regularly and then play a key role in maintain healthy India.

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