

From the Patron's Desk

Banning of drugs or modifying of the Drugs and Cosmetics Act – Where does the solution lies.



All the drug formulations are meant for prevention of ailments and diseases but few of them are lifesaving and essential and rests are substitutes for each other. When serious problems occur in health care there is always a “knee-jerk” response by many to impose a ban and thus provide an immediate and definitive response to the issue. Every year due to certain reasons the drugs are prohibited for manufacture and sale through gazette notifications under section 26A of drugs & cosmetics act 1940 by the Ministry of Health and Family Welfare and that trend followed in the present year 2016, also. The Health Ministry banned 344 fixed drug combinations through a gazette notification issued over the weekend. These include several common cough syrup solutions, analgesics and antibiotic combinations, many of which are sold over the counter. On the basis of the recommendations of expert committee and in exercise of powers conferred

by section 26A of the Drugs and Cosmetic Act, 1940 the Central Government hereby prohibited recently the manufacture for sale, sale and distribution for human use of fixed dose combination of drugs with immediate effects. The Health Ministry recently launched a drive to crack down upon irrational use of antibiotics and also notified a special schedule of drugs for which chemists will not only need to check the prescription before selling them but also maintain records with themselves or face government action. As per the Government concern, on the combined drugs, there is not much data available on drug-drug interaction and side-effects in FDC, India's system for collecting data for problematic drug reactions is weak. When multiple drugs from the same therapeutic group, like antibiotics, are clubbed together, it may lead to resistance. A lot combined drugs are sold in India are unapproved, given the lack of coordination between state and central regulators. Most important examples are over 70% of non-steroidal anti-inflammatory drug (NSAID) combinations, which are used as painkillers, were being marketed in India without central government approval. Further several single drugs are banned in India from 2000 onwards like Rofecoxib, Analgin, phenyl propanolamine, nimesulide, Terfenadine but still available in market and among that Rofecoxib, Analgin, nimesulide are rapidly selling drugs. The central government blames the manufacture, sale and distribution of harmful fixed dose combination medicines on the lax attitude of state governments. The health ministry issued a public notice in 2013, asking drug manufacturers to declare fixed dose combination medicines but a large chunk ignored the notice, and only 6,600 responded out of about 15,000 pharmaceutical units that are active in India, thinking probably Government will not take action. Hence In 2014, India set up a committee to review only those collected responded that had entered in the Indian market based on regulator's approval by the state and the policymakers gave a chance to the Pharmaceutical companies to retroactively prove the safety and efficacy of those combination drugs by submitted data. Based on the responses about the assessment data, a joint secretary at the health ministry announced that more than 300 drugs are prohibited to use by the Indian that are irrational. Two well known cough syrups i.e. Phensedyl, sold by US Company Abbott Laboratories and Corex, marketed by Pfizer Inc, India are also among them.

Unfortunately more than 80 per cent of Indian doctors prescribed drugs from the recently banned list of 344 drugs, revealed a survey conducted by eMedi Nexus, a doctor's network. This may be due to pressure from the pharma companies, attractive gifts, and biasness on non qualified medical representatives and so on. But after banned drugs notifications on gazette, around 60 % of doctors supported the steps taken by the Government. As per their views misuse of these combinations may be contributing to antibiotic resistance and causing the rise of some superbugs, strains of bacteria that have become resistant to antibiotics and secondly increased number of self medication by the people but Codeine and Nimesulide combinations were the main exceptions to the ban that doctors felt should have been made. India is a wider market share of combination drugs rather single drugs in the world but medical experts say most of them are irrational, that is they haven't been approved by the national regulator. Many aren't approved for sale in countries with more stringent regulation. The sale of such medicines is illegal because a combination drug needs to be cleared by the national regulator even if the individual constituents are pre-approved. They also added about special attention to be taken by the Government on drug price control policy in India. In contrast about 40 per cent of doctors disagreed with the government's justification

for the ban as per their views the reputation would be negatively impacted. Perhaps these combined drugs popularity in India is due to advantages such as increased efficacy, better compliance, reduced cost and simpler logistics of distribution. These are particularly useful in the treatment of infectious diseases like HIV, malaria and tuberculosis, where giving multiple antimicrobial agents is the norm. Interestingly, the combination of metformin+gliclazide+pioglitazone, which is used by diabetic patients and which was approved by the Drug Controller General of India, is very useful for diabetics. The government had approved it earlier, but banned now. There are 80 combinations of pioglitazone which are effective for diabetic patients and their ban is going to affect the patients.

With banning of 344 'Fixed Dose Combination' drugs leading to an immediate suspension of the manufacturing and sale of medicines, the chemists in India hit the panic button. Pharmacists fear that they would soon go out of business if sufficient time is not given to them before the implementation of the ban. Distributors want companies to take back stocks, Chemists fear raids by drug inspectors, Demand at least 45 days time to clear stock, these type of pressures are created to the industries. Removing the banned products from the market is going to be a daunting task. It is the largest ever recall in Indian pharmaceutical industry. The recall is going to be a considerable loss to the industry and could have done less haphazardly by the government. It will also result in significant drop in sales of retailers, said the pharmacy association. The ban could cost Indian pharmaceutical companies about Rs.3,500-3,800 crore, as per the analysts. Global giant Pfizer has already obtained a stay on the ban of its drug Corex while American pharmaceutical major Abbott indicated it will move court over its Phensedyl combination, the others are still contemplating legal action. The problem is that this time the government has listed each combination and banned them instead of issuing a bulk order. This means that each pharma company will have to separately go to court for each combination. Meanwhile, the government gazette gives minimum information about the reason for the ban. Even the new combinations are approved and only then released in the market. The Central government has been asked to submit the details for ineffectiveness of Corex and Phensedyl to the court as the report is not in public domain. Drug companies and industry associations used legal means to push back the government's order. The Drug Control Administration needs to go slow and not to go on a witch-hunt against pharmacists with drug inspectors raiding their stores.

In this stage the State Government should take special care for prohibiting of selling of those listed banned drugs. Government should amend the law periodically with the consent of regulatory bodies of other developed countries. The list of banned drugs should be clearly justified to the target professionals such as pharmacist, physician and manufacturers. Government should look after critical issues such as drug promotion, labeling regulation of the OTC drugs, marketing of irrational fixed drug combinations and banned drugs. There should be an involvement of all categories of health professionals in adverse drug reactions and pharmacovigilance planning. Regulatory authorities, healthcare professionals, researchers and pharmaceutical companies should join hands together to formulate guidelines for the fixed dose combination's to drive away fear from the minds of patients. Finally, before official declaration, Government has to discuss with drug control department and after taken judicial permission, the banned drugs are disclosed in the form of a Gazette which to be circulated all the health sectors.

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DOI : [10.18579/jpcrk/2016/15/2/97071](https://doi.org/10.18579/jpcrk/2016/15/2/97071)