Ban of fixed dose combinations may encourage nutraceuticals

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Fixed dose combinations (FDCs) refer to pharmaceutical preparations containing two or more drugs in a fixed ratio. They were conceptualised on the idea that certain drugs potentiate the action of other drugs when given together.

FDCs have to be very rationally and carefully prescribed, after because

1. Patient may not actually need those many drugs, thus he is subjected to additional side effects.

2. Some drug doses have to be individualised based on patient's response. You cannot do that if you are using FDCs.

3. Some companies have been selling FDCs in India under this pretext without consulting the Central government.

4. These non-essential FDCs thus do more harm than good by encouraging irrational and indiscriminate prescribing of more drugs than needed.

It is of utmost importance to stop production or marketing of irrational FDCs because in evolutionary terms, the drugs you give will kill the susceptible bacteria leading to selection of those strains which are resistant to the drug. When the drug resistant strains attack, the same drug will never work. Now as FDC has been given, other drugs in that FDC will not work well. This is very dangerous because we have limited types of antibiotics against any particular species of microbes.

The government has issued a notification on March 15, 2016 banning 344 FDCs. Over 2,000 branded drug products, involving these 344 FDCs, will now be off the shelf due to the ban. These 2,000 branded FDCs are used widely by diabetic, cardiac, psychiatric, asthmatic and other patients suffering from chronic diseases.

In an effort to stop this, the government has issued a notification on March 15, 2016 banning 344 FDCs. Over 2,000 branded drug products, involving these 344 FDCs, will now be off the shelf due to the ban. These 2,000 branded FDCs are used widely by diabetic, cardiac, psychiatric, asthmatic and other patients suffering from chronic diseases. All these patients are medically stabilised by these combo drugs for several years. Overnight ban and discontinuation of these products will undermine millions of patients on these medications.

It will be a major setback for pharmaceutical companies. People used to self-medicating using FDCs as well as physicians reliant on prescribing these will have to look for alternatives. The ban will have a negative impact on growth of Indian pharmaceutical sector and it will not only affect revenue, turnover and profitability of the drug companies but also weaken their R&D capability.

FSSAI does not have authority to disapprove nutraceutical products. According to law there is no prerequisite need of conducting clinical trials if it does not claim any health related benefits.

As a result, many pharma industries are inclined to produce and market more nutraceuticals rather than pharma drugs. One of the prime reasons of this unjustifiable law and regulation by Indian government on nutraceuticals, in addition to these banned FDCs, may also increase production of nutra drugs

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rather than pharma products. Competitive products of pharma companies have been facing difficulty to stay in the market. In addition, no innovative products are entering the market as there is shift towards production of nutraceuticals.

The unjustifiable laws and regulations market many irrational nutraceutical combinations which do not treat and do not play any role in improving the patient's condition. There is a well-known and highly marketed product FDC named metformin and Vitamin B12 for diabetic neuropathy which is a long term complication in case of type 2 diabetes mellitus. There is a good reason to make and improve a patient's condition with this combination but there are so many other combinations, having amino acid and other vitamins, also available in the market in addition of these two ingredients whose safety and efficacy has not been established.

Other important example is Vitamin E. There is documentary proof of effectiveness of Vitamin E in a dose of 200 mg RDA which is an antioxidant available in the market. With so many different dose strengths of Vitamin E (400 mg) available it is found to be a very high dose compared to the recommended daily allowance. Such a high dose can even generate free radicals which can further damage the cell and worsen the patients' condition.

Another good example is CVS disorder. Omega 3 fatty acid plays a vital role in lowering cholesterol but adding this with other amino acids and vitamins make this combination irrational because safety and efficacy of this is not established. One more example of marketing irrational combinations is of Vitamin B12 preparations with variable dose strengths. Only 1,500 mcg dose strength of RDA is rational in combination, rest combinations with different strengths are irrational. There is only one checkpoint regarding quality control by FSSAI (Food Safety and Standards Authority of India) before becoming nutraceutical product.

FSSAI does not have authority to disapprove nutraceutical products. According to law there is no prerequisite need of conducting clinical trials if it does not claim any health related benefits. So there is a huge gap in establishment of safety and efficacy data for nutraceuticals. Nutraceuticals prevent diseases. It does not cure diseases. In a nutshell there should be scientific evidence for approval of nutraceuticals. NS