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Government needs to stop speaking in different voices on FDCs

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Regulatory failure: The market is flooded with FDCs

Their inappropriate use poses a major threat to public health

The Jan Swasthya Abhiyan recently analysed 580 medicines being supplied under the Pradhan Mantri Bharatiya Janaushadhi Pariyojana (PMBJP), and found that over 100 of these were Fixed Dose Combinations (FDCs), many of them irrational.

FDCs are two or more medicines combined in fixed proportion in a single dosage form (tablet, capsule, syrup and so on). This revelation comes a few weeks after the government signalled its intention to ensure rational prescription of medicines by sending out stern directives requiring doctors to prescribe by generic names.

Clearly, different wings of the government are working at cross purposes—one requiring strict adherence to rules regarding rational prescription, and the other allowing sale of irrational FDCs from its own Janaushadhi outlets. Currently, the government is also defending, in the Supreme Court, a ban on 344 FDCs that it had imposed, and which was challenged by drug companies and overturned by the Delhi High Court in December 2016.

We have different scenarios regarding use of FDCs in India—rational use of rational FDCs, irrational use of rational FDCs, and irrational use of irrational FDCs. The problem is compounded by a dysfunctional drug regulatory system that has resulted in the market being flooded with a large number of FDCs. Estimates indicate that almost 50 per cent of drugs consumed are FDCs, a much larger volume than what one would expect if FDCs were prescribed rationally. A study published in 2015 in *PLOS Medicine* found that of 175 FDCs studied, only 14 were approved in the UK and 22 in the US.

Three factors appear to be responsible for the Indian market being flooded with FDCs. Over time, companies have resorted to the marketing of FDCs to circumvent price control: they prefer to market FDCs that are not under price control rather than single-ingredient drugs under price control. The second is what is called ‘me too’ marketing. Companies vie with one another for a share of the market for the same class of drugs. In order to provide something ‘new’ to prescribers, they develop and market FDCs (often irrational, but promoted as a unique and innovative product by each company) purely for commercial reasons, and support its sales through sophisticated (and often unethical) marketing strategies.

Finally, an understaffed and inefficient drug regulatory agency contributes to the problem by allowing irrational FDCs in the first place and then by not taking action to ban them.

The 59th report of the Parliamentary Committee on Health and Family Welfare had pointed out that in 2012 the Central Drugs Standard Control Organization (CDSCO) had, by various acts of omission and commission, failed to restrict the number of irrational FDCs.

A glaring omission pointed out was that many FDCs were being marketed after receiving approval from State regulatory agencies, whereas marketing approval can only be provided by the CDSCO.

While every FDC needs to be treated as a new drug, and its safety and efficacy needs to be substantiated, this requirement was not adhered to in a large number of marketing approvals for FDCs. While the CDSCO imposed a ban on 344 FDCs in 2016, public health groups aver that the FDCs banned account for only a fraction of the FDCs currently being marketed.

Inappropriate use of FDCs poses a major threat to public health: they can lead to additional toxicity, limit choice of prescribing physicians, increase treatment cost, lead to under- or overdosing and, in the case of antibiotics, FDCs can contribute to more rapid development of antimicrobial resistance. It is to be hoped that the government will act to harmonise its own policy prescriptions, and take a firm position against the rampant use of irrational FDCs.

The writer is National Convenor, Jan Swasthya Abhiyan. Views expressed are personal.

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