Deadly drug cocktails in India

Indians are big consumers of dangerous fixed dose combinations (FDCs) that are not approved by the country's drug regulator, says a study, 'Threats to global antimicrobial resistance control: centrally approved and unapproved antibiotic formulations sold in India', published in the *British Journal of Clinical Pharmacology*.

FDCs are a blend of two or more drugs to maximise drug efficacy and can promote antibiotic resistance if they are not designed rationally. Using statistics from the PharmaTrac sales database, the study found that of the 118 FDCs sold in India, only 43 were approved by the Indian drug regulator, the Central Drugs Standard Control Organisation (CDSCO), while five were approved by the U.S. and the U.K. regulators.

Seven of the FDCs that were not approved by the CDSCO were among the top 20 bestselling FDCs in 2011-12. Sixteen of these bestsellers were not approved in the U.S. and the U.K. either. For example, the second-most popular Indian FDC, a combination of ofloxacin and cloxacillin, is not approved by the CDSCO. The study also identified approved drugs that were irrational — ofloxacin and the anti-protozoa drug ornidazole were combined even though they had different dosing schedules and could worsen diarrhoea.

Around 42% of the FDCs sold in India in 2011-12 included at least one "highest priority critically important antimicrobials" as designated by the World Health Organisation. These are antibiotics that are a last resort, where loss of efficacy would have a large impact on public health. Eight of these combinations included two antibiotics, and only two of the eight were approved in India, while none were approved in the U.S. and the U.K. While the idea behind antimicrobial combinations is to reduce the risk of resistance by attacking a bacterium from two fronts, studies have shown that if the two drugs aren't carefully chosen, combinations can trigger resistance to multiple antibiotics.

In March 2016, the Union government banned 344 FDCs. The Supreme Court, while upholding the ban after appeals from pharma companies, has asked the Drugs Technical Advisory Board to examine the cases afresh. Of the 344 FDCs, the study's authors identified 16 in the PharmaTrac database. Several multinationals were found to be selling unapproved FDCs in India as well.

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