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INDIA'S ALARMING 'FIXED DOSE COMBINATION' PROBLEM

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'The FDC problem has been on the regulatory radar since 1978' | Photo Credit: Getty Images

A group of academics from India, Qatar and the United Kingdom recently published a worrying new study in the Journal of Pharmaceutical Policy and Practice (2023, 16:39) on the volume of unapproved and even banned fixed dose combination (FDC) of antibiotics that are being sold in India. Using sales data of the pharmaceutical industry, the study documents that in the year 2020, 60.5% FDCs of antibiotics (comprising 239 formulations) were unapproved and another 9.9% (comprising 39 formulations) were being sold despite being banned in the country. That so many of these unapproved or banned FDCs contain antibiotics is alarming because of the increasing prevalence of antibacterial microbial resistance (AMR) in India.

FDCs are combinations of one or more known drugs and can be useful in the treatment of some diseases since the combination can improve patient compliance. For instance, if a patient has to take three different medications for a particular treatment, she may forget to take one. But if all three medications are combined into one tablet or one syrup, the chance of her forgetting to take one or two of the drugs is reduced. For diseases such as AIDS, it is well documented that FDCs have proven to be very useful in improving patient compliance, which at the end of day improves treatment outcomes.

Making FDCs, even though most consist of drugs with known safety and efficacy profile, is not an easy job. All drugs have side effects and when formulated together, there is a possibility that the active ingredient or even the excipients (inactive ingredients) may affect the way that each drug functions. For example, the drugs may interact in a way to reduce the therapeutic efficacy of each active ingredient, or, worse, the drugs may interact with each other to create a more toxic element, often called metabolites. This is why it is crucial that all FDCs go through a scientifically designed approval process where such interactions can be evaluated.

Pharmaceutical companies in India use these FDCs to escape liability under multiple laws without much concern for public health. One such law is the Drugs (Prices Control) Order (DPCO), under which the government fixes the prices of individual drugs. Since drug combinations were traditionally not covered under the DPCO, the pharmaceutical industry decided that making FDCs provided an easy way to escape the remit of the DPCO.

Also read |Manufacture and sale of 344 FDC drugs banned

Driven by this cold logic of the market, and not public health, the Indian pharmaceutical industry introduced an astounding variety of FDCs that lacked any medical rationale. For example, anti-inflammatory drugs were combined with vitamins, anti-histamines were combined with anti-diarrhoeal agents, penicillin was combined with sulphonamides, and vitamins were combined with analgesics. These were combinations not found in any other country.

There were two added advantages of adopting this strategy for the industry. The first, the fact that because of the bewildering variety of FDCs being sold in the market, there were no standards set by bodies such as the Indian Pharmacopoeia Commission for testing these drugs for quality of manufacture. When there are no standards recognised by the law, there is no question of manufacturing “not of standard quality” drugs, and hence there is no possibility of prosecution under the Drugs & Cosmetics Act, 1940. At most, when these FDCs are sampled in the market and sent for testing, the usual protocol for government laboratories conducting such tests is to write to the manufacturer and ask for their own protocols to test the drug. In other words, the pharmaceutical industry gets to provide its own standards in order for the government to test their drugs.

The second advantage of going down the FDC route is that it gives individual companies a reason to charge higher prices for their drugs. For example, if 20 different pharmaceutical companies were manufacturing and selling a drug such as azithromycin, they would have to compete furiously and reduce prices to capture a larger share of the market. But if they combine azithromycin with another drug, for example, cefixime to create a FDC, they can claim it as a new unique product catering to a specific need, thereby allowing them to charge a higher price until others introduce similar products, at which point the first mover may try to create a new FDC. When the market and the regulatory structure rewards these manufacturers of such pseudo-innovation rather than for discovering and developing true innovative medicines, this is what happens. These dubious FDCs can command higher prices. Of course, none of this is possible without doctors who are willing to prescribe such FDCs. While it is tempting to paint all such doctors as corrupt, the fact of the matter is that most doctors wrongly presume that the drug regulator is doing its job when a product is sold on the market.

The FDC problem has been on the regulatory radar since 1978 when the first government committee studied the issue and admitted that we had a problem on our hands. At the time, there was no system under the colonial-era Drugs and Cosmetics Act, 1940 to vet drugs for safety and efficacy prior to their sale in India. This meant that each State drug controller could hand out manufacturing licences for any drug formulation and there was little that the central government could do to stop their sale.

In 1982, Parliament changed the law to give the central government the power to “prohibit” the manufacture of specific drugs that lack therapeutic value or justification. Later in that decade, in 1988, the central government amended the rules to introduce a new requirement for manufacturers of all “new drugs”, including FDCs, to submit proof of safety and efficacy to the Drugs Controller General of India (DCGI) who heads the Central Drugs Standard Control Organization (CDSCO). These amendments also made it clear that State drug controllers could not grant “manufacturing licences” for “new drugs” that are not approved for safety and efficacy by the DCGI.

Despite the law being crystal clear on the issue, State drug controllers have simply ignored the law to continue issuing manufacturing licences for FDCs not approved by the DCGI with impunity. The manufacturers selling these FDCs that have not been approved by the DCGI can technically be prosecuted by the Central government for violating the law.

Instead of ordering criminal prosecutions, the Ministry of Health is playing a game of whack-a-

mole by constantly invoking its powers under Section 26A to prohibit the manufacture of specific FDCs. It has issued 444 orders under this provision since 1983, banning mostly FDCs. Many of these orders have been embroiled in complex litigation, with the courts muddying the waters with inconsistent decisions.

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The fact that these academics have discovered 239 unapproved FDCs being sold in 2020 in just one category of FDCs (their previous studies have revealed similar unapproved FDCs in other therapeutic categories), more than 42 years after the problem was first flagged is an astonishing indictment of the incompetence of the drug regulatory framework in India. As they point out in their paper, unregulated FDCs may end up contributing to the AMR problem in India. It is vital for the Ministry of Health to take immediate action.

Dinesh S. Thakur and Prashant Reddy T. are the co-authors of* The Truth Pill: The Myth of Drug Regulation in India *(2022)

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