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‘MANY COMBINATION DRUGS NOT APPROVED BY REGULATOR’

Relevant for: Indian Polity & Constitution | Topic: Regulatory bodies

Of the 110 anti-TB (tuberculosis) Fixed Dose Combinations (FDCs) available in India, only 32 (less than 30%) have been approved by the Central Drugs Standard Control Organisation (CDSCO), the country’s drug regulator. In the case of malaria FDCs, only eight out of 20 (40%), have been approved.

These statistics, that give rise to safety and efficacy concerns, have been brought out in a study published online in the journal *Tropical Medicine and International Health* by researchers from the Manipal College of Pharmaceutical Sciences.

An FDC or combination product is a formulation with more than one active pharmaceutical ingredient (API) in a fixed ratio of doses formulated into a single dosage form.

Proportion, sales

Aimed at assessing the proportion and sales of unapproved FDCs of anti-tubercular, antimalarial and antiretroviral (anti-HIV/AIDS) medicines available in India, the study analysed the available FDCs for these diseases and screened them against the CDSCO database of approved FDCs.

Swapnil J. Dengale from the Department of Pharmaceutical Quality Assurance in the Manipal College of Pharmaceutical Sciences, the corresponding author of the study, told *The Hindu* that “an opaque regulatory framework and ambiguity over licensing powers have contributed to the problem. The rationality of unapproved FDCs should be reviewed and irrational formulations should be banned.”

“As of April, the CDSCO had approved 1,288 FDCs. This is disproportionately high compared with the availability in a tightly regulated market like USFDA, which has only a few hundred approved FDCs.”

Pointing out that even the World Health Organisation’s (WHO) list of essential medicines mentions only 24 FDCs, Dr. Dengale said: “It is unfortunate that a majority of approved FDCs in the Indian market are irrational and lack scientific justification. The scientific rigour of the CDSCO in approving these FDCs has been questioned time and again in Parliamentary and academic reports.”

The study quoted the Parliamentary Standing Committee on Health and Family Welfare, which in its 59th report in 2012, pointed out multiple deficiencies in the CDSCO’s approval process for FDCs. It highlighted institutional problems such as understaffing, lack of skills, and inadequate infrastructure. “However, the most significant observation concerned the issuance of manufacturing licenses by the State Licensing Authority without the prior clearance of the Drug Controller General of India DCG(I), the head of CDSCO. This is the main problem,” he said.

The problem of unapproved FDCs mainly affects those who get treated in the private sector. “In the absence of a strong pharmacovigilance mechanism in India, there is no data on adverse events of these unapproved FDCs,” the authors added.

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