Many combination drugs not approved by regulator

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‘Many combination drugs not approved by regulator’-Study raises safety, efficacy concerns; calls for ban on irrational formulations

- 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.

Parliamentary Standing Committee on Health and Family Welfare Report

- 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 problem of unapproved FDCs mainly affects those who get treated in the private sector.
- In the absence of a strong pharma covigilance mechanism in India, there is no data on adverse events of these unapproved FDCs.

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