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(P)

Many Indian drug combos harmful, not needed: Study

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Mumbai: A study in reputed medical journal Lancet has ripped apart India's drug regulatory system and the domestic pharma industry, claiming that the Indian Drug Act makes it possible for harmful fixed dose combinations (FDCs) to evade both approval and price controls.

The study highlights the proliferation of irrational and harmful combination drugs, many of which are available without necessary clinical trials, and with little medical rationale.

The findings, shared exclusively with **TOI**, show that there is hardly any evidence to support the use of these drug combinations and suggest that the regulator should withdraw all licences until the manufacturers provide scientific rationale for their safety.

"India's Drug Act makes it possible for FDCs (fixed dose combinations) to evade CDSCO (Central Drugs Standard Control Organization) approval and is in urgent need of an overhaul," Lancet says in its analysis.

Though fixed dose combinations of metaformin, used for managing diabetes, are not recommended by international or national treatment guidelines for diabetes control, over 500 marketed brands are available in the country. Some of the top-selling metformin combination medicines include Amaryl MP, Gemer P1, Glimy M, Glyciphage PG1 and Pioglar GF.

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'Ban dubious drug combos'

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A Lancet study, which raps India's drug regulatory system and the local pharma industry, says though there is little use of metformin combinations globally, over 500 marketed brands are available in India.

"Many such dubious drug combinations should be banned, and taken off the market. Strict criteria and testing should be applied to screen any new FDC (fixed dose combination), and also background and past performance of manufacturing company should be strictly monitored," says Dr Anoop Misra, chairman of Fortis CDOC (hospital for diabetes and allied specialities).

Although 41 metformin FDCs have been approved for diabetes in India, the rationale (for their approval) is not clear as the drug regulator does not publish grounds for new drug approvals, while the country's clinical trials registry, which has been mandatory only since 2009, has no data of these trials conducted in

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India. Sales volumes of metformin FDCs outstrip metformin (single drug) formulations by a factor of three to one, and account for 56% of all oral diabetic drug sales, while disturbingly, only one of these is marketed outside India.

"Our research shows the short-duration trials sponsored by MNCs failed to consider the balance of any possible advantage of FDCs over potential disadvantages, and didn't provide robust evidence of the efficacy and safety of these combinations. Furthermore, when these trials were scrutinized against WHO guidelines for approval of FDCs, none met the criteria for efficacy and safety. We concluded that CDSCO must make public the evidence it used when granting approval of metformin FDCs and the basis for efficacy and safety," Lancet says.

Earlier, an expert committee chaired by Ranjit Roy Chaudhury stated that about 85,000 drug formulations available here should not be marketed at all since the scientific basis for their approval is in need of urgent review.

For the full report, log on to www.timesofindia.com

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