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DAILY EDITORIAL ANALYSIS

TOPIC

India's Fixed Dose Combination Problem

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Context

- A group of academics from India, Qatar and the UK recently published a new study on the volume of unapproved and banned **Fixed Dose Combination (FDC) of antibiotics** that are being sold in India.

Fixed Dose Combination (FDC)

- FDC drugs are those which contain a combination of two or more active pharmaceutical ingredients (APIs) in a fixed ratio.
- It 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.

Benefits

- Fixed-dose combination (FDC) therapies offer a means to simplify complex treatment regimens, and have several advantages that help patients reach their glycaemic goals.
- Greater efficacy compared with higher dose monotherapy
- Reduced risk of adverse reactions relative to higher dose monotherapy
- Lower overall costs
- Improved medication concordance.
  - 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.

Issues and Concerns

- The Indian pharmaceutical industry introduced an astounding variety of FDCs that lacked any medical rationale.
- There were no standards set by bodies such as the Indian Pharmacopoeia Commission for testing these drugs for quality of manufacture.
- **Pharmaceutical companies** in India use these **FDCs to escape liability** under multiple laws without much concern for public health.
  - The FDC route gives individual companies a reason to charge higher prices for their drugs.
- All drugs have side effects and when formulated together, there is a possibility that the **active ingredient or even the excipient**s (inactive ingredients) may affect the way that each drug functions.
- According to study ,in the year 2020, 60.5% FDCs of antibiotics were unapproved and another 9.9% were being sold despite being banned in the country.

Steps of Government

- 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.
- The Centre has banned 14 fixed dose combination (FDC) drugs in the country under section 26 A of the Drugs and Cosmetics Act, 1940 saying that there is "no therapeutic justification" for these medicines and they may involve "risk" to people

Conclusion and Way Forward

- The general guidance for the clinical development and approval of FDC drugs in India is not much standardised.
  - For rationale approval, the central and state regulators must harmonize their procedures for licensing FDCs.
- All new and existing FDC products should be subjected to submission of long term safety surveillance through closely monitored national level postmarketing studies.
- Drug laws need to be amended to ensure the safety and effectiveness of medicines marketed in India.
- It is crucial that all FDCs go through a scientifically designed approval process where such interactions can be evaluated.
- Making FDCs, even though most consist of drugs with known safety and efficacy profile, is not an easy job.
  - It is vital for the Ministry of Health to take immediate action.

DAILY MAINS QUESTION

Do you agree with the view that Fixed Dose Combination (FDC) may end up contributing to the Antimicrobial resistance problem in India? Give arguments in favour of your answer.

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