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## 328 Fixed Dose Combinations Drugs Banned by Government

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The Ministry of Health and Family Welfare has recently prohibited the manufacture for sale, sale or distribution for human use of 328 FDCs through the powers conferred by section 26A of the Drugs and Cosmetics Act, 1940.

### Background

- In March 2016, Central Government had prohibited the manufacture for sale, sale, and distribution for human use of 344 FDCs.
- However, drug manufacturers dragged Central Government to court over its order. As per the directions given by the Supreme Court in December 2017, the matter was examined by the Drugs Technical Advisory Board (DTAB).
- The Drugs Technical Advisory Board recommended that there is no therapeutic justification for the ingredients contained in 328 FDCs and these FDCs may involve risk to human beings.

### Fixed Dose Combinations (FDCs)

A fixed-dose combination or FDC drug contains two or more active ingredients in a fixed dosage ratio.

### Benefits of FDC's

- The basic rationale of making “fixed-dose combination” medicinal products is either to improve patient compliance or to benefit from the synergistic effects of the two medicinal products given together.
- FDCs have shown to be particularly useful in the treatment of infectious diseases like HIV, malaria, and tuberculosis where giving multiple antimicrobial agents is the norm.
- FDCs are known to offer specific advantages over the single entity preparations, such as increased efficacy, and/or a reduced incidence of adverse effects, possibly reduced cost and simpler logistics of distribution relevant to situations of limited resources.

## **Issues related to FDCs**

- FDCs are the combination of two or more drugs, there might be the case that the patient may not actually need those many drugs, thus he is subjected to additional side effects.
- Some drug doses have to be individualized based on patient's response. It is not possible in FDCs.
- Some companies have been selling FDCs in India without proper clinical trials and government approvals. Thus, it is necessary to regulate them.
- These non-essential FDCs thus do harm by encouraging irrational and indiscriminate use by peoples. Irrational use of FDCs of antibiotics is among the major causes of antibiotic resistance in India.

## **Drugs Technical Advisory Board**

- Drugs Technical Advisory Board is a statutory body constituted under the Drugs and Cosmetics Act, 1940.
- The function of DTAB is to advice Central government and State government on technical matters related to drugs and cosmetics.