Ban on Fixed-dose Combination Drugs

Why in news?

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The Drug Technical Advisory Board has recommended banning 343 “irrational” fixed-dose combination (FDC) drugs

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What are FDC drugs?

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- An FDC drug is one that contains two or more active ingredients combined in a fixed dose to form a single drug.
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- Several cough syrups, painkillers and dermatological drugs in India are FDCs.
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- Some are marketed with licenses approved only by state regulatory agencies instead of the Drug Controller General of India.
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- These FDCs could be irrational and unsafe for consumption, with potential health risks.
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- Rampant use of FDCs has allowed antibiotic resistance to assume threatening proportions in India.
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- However, not all FDCs are unsafe as some are crucial to treat chronic illnesses like diabetes and HIV.
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How did the issue evolve?

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- **Ban** - In 2016, the Ministry of Health and Family Welfare had implemented a ban on 349 FDCs.

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- It included popular brands like Saridon, Corex, D Cold Total, and Vicks Action 500 Extra, etc.
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- The government says there are enough single drug alternatives that are safer and effective.
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- **Committee** - The ban was based on recommendations of the Chandrakant Kokate committee.
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- It said FDCs are "unsafe" and "irrational" for consumption, posing health risks.
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- **Court** - On pharma companies challenging the ban, the matter was taken to the Supreme Court.
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- Drug makers argued that the statutory bodies on drug regulations were not consulted before the ban.
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- Eventually, the Supreme Court referred the matter to the Drug Technical Advisory Board (DTAB).
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- It directed the DTAB to make a fresh review of the issue with fixed-dose combination drugs.
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What are DTAB's findings?

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- Most of the pharma companies had not generated safety and efficacy data of their own for their FDCs.
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- Almost 95% of the appellants failed to prove safety, rationality and compatibility of these FDCs.
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- The indications for which these FDCs were mentioned were too "vague" and not "as per treatment guidelines."
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- For most FDCs, their use would lead to "unnecessary over use".
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- So, patients would be exposed to risk of multiple ingredients, when actually one would suffice.

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- Over the years, India has become a dumping ground for irrational FDCs that are not approved in other countries.
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- **Decision** - The DTAB in a meeting held recently re-inforced the ban on 343 of the 349 drugs.
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- It, however, felt restricted use could be allowed for six FDCs.
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- The DTAB would forward its report to the health ministry soon.
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What are the implications?

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- The market size of the banned drugs is estimated to be around Rs 20-22 billion.
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- The ban, if comes into force, will thus impact the country's top drug-makers.
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- These FDCs roughly contribute to 1.8% of the overall domestic drug market.
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- The FDC segment is already on a slower growth rate (4.7% in June) compared to the rest of the domestic drug market (8.6%).
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- These 343 FDCs are only a small portion of the FDCs that are sold in the country.
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- The bigger uncertainty would be the additional 944 FDCs that were identified by the Kokate committee as being irrational.
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- The DTAB may look at these products now, and the coverage of the ban is expected to expand.
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Source: Economic Times, Business Standard

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Quick Fact

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Drugs Technical Advisory Board

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- DTAB is the apex body to decide on technical matters related to drugs in the country.
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- It is constituted as per the Drugs and Cosmetics Act, 1940.
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- It functions as part of the Central Drugs Standard Control Organization (CDSCO) in the Ministry of Health and Family Welfare.
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