Ban on harmful drugs

What is the issue?

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Even after giving its assurance on banning 37 harmful drugs, government is yet to take a considerable action on it.

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What is a fixed dose combination drug?

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- Combination drugs or fixed dose combination (FDC) drugs are those with two or more active pharmaceutical ingredients combined in a fixed dose to form a single drug.
- Commonly used medications such as paracetamol, aceclofenac and nimesulide are FDC.
- Government following the recommendation of the Kokate committee banned 344 fixed dose combination medicines many of which are household names.
- Under Section 26A of the Drugs Act, a drug can be banned only after the licence holder of that drug is given a three-month notice.
- But government said, these drugs were banned due to their ability to cause “antibiotic resistance”.
- Later the Delhi high court struck down the ban stating that the government had acted in a “haphazard manner”.
- Still many such FDC’s exist in India.

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What is antibiotic resistance?

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- Antibiotic resistance is the ability of a microorganism, which is causing the disease, to withstand the effects of an antibiotic medicine.
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- Indiscriminate prescription of antibiotics and laxity of enforcement laws are the main causes of antimicrobial resistance.
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What is the function of DCGI?

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- Drug Controller General of India under the gamut of Central Drugs Standard Control Organization is responsible for approval of licenses of specified categories of drugs such as blood and blood products, IV fluids, vaccines and sera in India.
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- DCGI lay down the standard and quality of manufacturing, selling, import and distribution of drugs in India.
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- It acts as an appellate authority in case of any dispute regarding the quality of drugs.
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- It prepares and maintains national reference standard.
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- It brings about the uniformity in the enforcement of the Drugs and Cosmetics Act.
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- It trains Drug Analysts deputed by State Drug Control Laboratories and other Institutions.
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What is the significance of banning?

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- Department of Health Research (DHR) requested the Drug Controller General of India (DCGI) and senior health ministry officials last year with a request to ban 37 drugs that termed to be “very harmful”.

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- But these drugs continue to be freely available in the market.
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- The DCGI suggested to the health ministry that a committee should be formed to look into this matter.
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- But no such panel had been formed till date.
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- The 37 fixed-dose combinations (FDCs) listed by DHR are commonly used antibiotics.
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- e.g Cefpodoxime & Clavulanate - used to treat diseases like pharyngitis, urinary tract infection, gonorrhea and pneumonia.
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- This drug is sold by more than 70 companies in India under different brand names.
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- Due to these drugs there is a risk of increase in antibiotic resistance in India.
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Source: The Indian Express

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