Weeding out Unregulated Drugs

What is the issue?

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- Various new drugs and combination medicines that are currently available in the market haven’t got the necessary regulatory approvals.
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- Drug Controller General of India (DGCI) has State regulators to review and recall such medicines immediately.
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What did the recent directives come up?

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- Recently, raids were conducted by the Central Drugs Standards Control Organisation (CDSCO) on some manufacturing plants in Uttarakhand.
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- It emerged that 70 of the 118 products that were manufactured were without the DCGI approval, though they had been licensed by the State authorities.
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- This was in contravention to law as new drug are not supposed to be manufactured without the approval of the central drug regulator.
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- State authorities have been asked to not give manufacturing approvals for new drugs and combination medicines without DGCI consent.
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What are combination medicines and what is their status?

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- Combination medicines are ones that combine 2 or more dosages in fixed proportions in order to address illness that often accompany each other.
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- Currently, even if Fixed Dose Combinations (FDC) of already approved drugs is to be released, it needs prior DCGI approval.
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- Notably, the union government had also banned of 344 FDC Drugs in 2016 as they found them to be unsafe despite individual doses being safe.
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- While the Supreme Court upheld the same in subsequent litigations, compliance wasn't strictly forced on the pharma manufacturers by the states.
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- Significantly, of 118 different FDC formulations sold in India between 2007 and 2012, it was found that only 43 were approved by the central regulators.
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- It is to be noted that, the 118 FDC formulations were sold in over 3300 branded products made by about 500 different pharmaceutical manufacturers.
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What is the way ahead?

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- There are big risks for the society at large as unregulated dosages could affect patient health as well as promote drug resistance among microbes.
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- Multinational companies were found to be manufacturing many unapproved formulations, despite pledging to tackle rising antimicrobial resistance.
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- Drug resistance emerges as a result of erratic consumption of drugs that aid microbes to become immune to drugs and makes tackling illness tough.
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- Hence, state regulatory authorities should ensure that they don't approve any FDC drug without DCGI clearance and also ensure manufacturer compliance.
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Quick Facts

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Central Drugs Standard Control Organization (CDSCO):

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- CDSCO is the national regulatory body for pharmaceuticals and medical devices in India.
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- It is divided into zonal offices which do pre-licensing and post-licensing inspections, post-market surveillance, and recalls when needed.
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- **Drug Controller General of India (DCGI)** is an organ of the CDSCO which is responsible for approving and licensing of drugs and medical devices.
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- The DCGI is advised by the Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC).
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Source: Business Line

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