Weeding out Unregulated Drugs

What is the issue?

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

What did the recent directives come up?

- Recently, raids were conducted by the Central Drugs Standards Control Organisation (CDSCO) on some manufacturing plants in Uttarakhand.
- 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.
- This was in contravention to law as new drug are not supposed to be manufactured without the approval of the central drug regulator.
- State authorities have been asked to not give manufacturing approvals for new drugs and combination medicines without DGCI consent.

What are combination medicines and what is their status?

- Combination medicines are ones that combine 2 or more dosages in fixed proportions in order to address illness that often accompany each other.
- Currently, even if Fixed Dose Combinations (FDC) of already approved drugs
is to be released, it needs prior DCGI approval.

- Notably, the union government had also banned 344 FDC Drugs in 2016 as they found them to be unsafe despite individual doses being safe.
- While the Supreme Court upheld the same in subsequent litigations, compliance wasn’t strictly forced on the pharma manufacturers by the states.
- 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.
- It is to be noted that, the 118 FDC formulations were sold in over 3300 branded products made by about 500 different pharmaceutical manufacturers.


What is the way ahead?

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


Quick Facts

Central Drugs Standard Control Organization (CDSCO):
CDSCO is the national regulatory body for pharmaceuticals and medical devices in India.

It is divided into zonal offices which do pre-licensing and post-licensing inspections, post-market surveillance, and recalls when needed.

**Drug Controller General of India (DCGI)** is an organ of the CDSCO which is responsible for approving and licensing of drugs and medical devices.

The DCGI is advised by the Drug Technical Advisory Board (DTAB) and the Drug Consultative Committee (DCC).

Source: Business Line