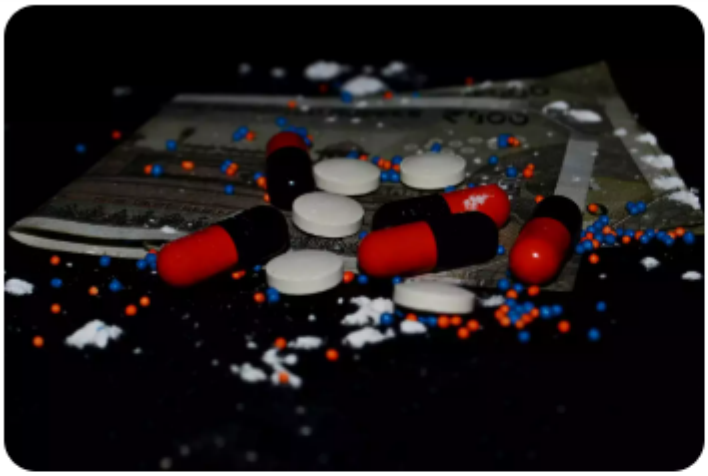
Govt bans manufacture, sale of 35 fixed-dose combination drugs

The regulator issued the directions after it found that certain FDC drugs have been licensed for manufacture, sale, and distribution without prior evaluation of safety and efficacy, posing a serious risk to public health and safety.



New Delhi: Apex drugs regulatory body CDSCO has directed drug controllers of all states and Union territories to stop manufacture, sale and distribution of unapproved 35 fixed-dose combination drugs that include painkillers, nutrition supplements and anti-diabetics. They have also been asked to review their approval process for such fixed dose combination drugs (FDC) and ensure strict compliance of the provisions of the Drugs and Cosmetics Act 1940 and rules.

FDC drugs are those which contain a combination of two or more active pharmaceutical ingredients (APIs) in a fixed ratio.

The regulator issued the directions after it found that certain FDC drugs have been licensed for manufacture, sale, and distribution without prior evaluation of safety and efficacy, posing a serious risk to public health and safety.

In a communication sent on April 11, Drugs Controller General of India (DCGI) Dr Rajeev Raghuvanshi referred to the letter issued by his office on January 2013 where concerns were raised regarding the grant of manufacturing licenses for sale of FDC drugs that fall under the definition of a "New Drug" in the country without due approval from DCGI.

The same concern has been raised from time to time and multiple letters have been issued to the respective state licensing authorities that granted permission for manufacturing and marketing of unapproved FDCs. The most recent such letter was issued in February this year.

"It has come to the notice of this directorate that certain FDC drugs have been licensed for manufacture, sale, and distribution without prior evaluation of safety and efficacy as per the provision of NDCT Rules 2019 under the Drugs and Cosmetics Act 1940. This poses a serious risk to public health and safety," the letter stated.

The approval of such unapproved FDCs compromises patient safety and may lead to adverse drug reactions, drug interactions, and other health hazards due to the absence of scientific validation, the letter underlined.

Upon issuance of show cause notices to the manufacturers, they have stated that these licenses were granted by the respective drug licensing authorities and have not violated any rules, it said.

This has resulted in a lack of uniform enforcement of the provision of NDCT Rules 2019 under the Drugs and Cosmetics Act 1940 across the country, the letter pointed out.

"In view of the above, all state and union territory drug controllers are requested to review their approval process for such FDCs and ensure strict compliance of the provisions of the act and rules," the letter said.

The letter also listed out 35 unapproved FDCs which were earlier licensed by state/ UT drug controllers for manufacture, sale, and distribution without evaluation of safety and efficacy by Central Drugs Standard Organisation (CDSCO) and later on cancelled by Drug Licensing Authorities (SLAs) or voluntarily surrendered by manufacturers following the issuance of show cause notices for reference.

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