

## Regulator Mulls Changes in Labelling Norms for Drugs

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India's drug regulator is considering changes in the norms for labelling medicine packs after some state drug controllers raised concerns that consumers may be getting misled by the way marketing companies are displaying their names on packs.

Officials at the Drug Controller General of India (DCGI) said the changes in the norms will ensure that consumers do not mistake the marketing firm to be the manufacturer of the drug.

"We are considering different options on labelling norms, including different sized fonts for the marketing firms and manufacturers, so that while buying the drug, people can make an informed decision about who is the manufacturer of the drug and who is marketing it," an official at the DCGI told ET. The official, who requested anonymity, said stakeholders will be consulted on the feasibility of various options before a final decision is taken on the matter.

State drug regulators had recently raised concerns on the varied formats of labelling on drug packs.

At a recent meeting of the drug consultative committee, the drug regulator of Andhra Pradesh said it

has come across several instances where large pharma companies, which are only marketing products manufactured by smaller and lesser known firms, print their own names in bold fonts, giving the impression that the drugs have been manufactured by them. Drug regulators of several other states supported this contention.

At present, rules under the Drugs and Cosmetics Act do not explicitly bar the marketing company from printing its name in any way along with the original manufacturer.

Members of the drug consultative committee, which is an advisory body on drug regulations, "recommended that a provision may be made in the rules that the label of the drug formulation should not contain any other information except for what is required under the Drugs and Cosmetics Act and rules, or is required to be given in compliance to any other Act in force", according to the minutes of the meeting.

"If the proposal on differentiated fonts is mandated, it will work to the advantage of the smaller players over a period of time, by creating familiarity with the names of their companies in trade channels and among consumers," said Amit Chander, partner, healthcare, Baring Private Equity Partners, India.

*Regulatory*