

## REGULATORY GUIDELINES

# Drug industry divided over govt move on statutory marketing code

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**D**rug makers are divided over the government's plan to introduce a statutory marketing ethics code, with foreign pharmaceutical companies supporting the initiative and local drug makers opposing it.

While the lobby group representing local pharmaceutical companies prefer self-regulation over mandatory legislation, foreign drug companies have suggested it should make the marketing ethics code statutory.

The department of pharmaceuticals plans to make its drug marketing guideline a mandatory code to be followed by all as unfair trade practices, including the nexus between pharma companies and doctors to push up drug prescription and other types of exploitation, are on the rise. The government department, responsible for policy and regulations related to drug manufacturing and sales in the local market, is contemplating introducing a special regulatory framework including provisions for strict action against violators, *Mint* reported on Friday.

The proposal may deter those that are flouting the fair practice guideline, a pharma marketing consultant said, requesting anonymity. Industry lobbies, which had come out with their own guidelines in this regard, had also proposed setting up of internal ethics panel or ombudsmen both at the industry level and at an individual company level to keep a tab on unethical practices. Officials from the department of pharmaceuticals had said last week that the government will



**Seeking transparency:** The govt plans to make its drug marketing guideline a mandatory code to be followed by all as unfair trade practices.

give the industry six months to demonstrate the effectiveness of their voluntary measures.

"This is top on the agenda for the department now and it's just awaiting clarity in the ethical rules of MCI (Medical Council of India), which is the statutory body to regulate medical doctors," one official had said last week. MCI prohibits its members from indulging in unfair practices, including receiving gifts and other rewards from pharma companies, exploiting patients for financial benefits and taking kickbacks from pharmacies and diagnostics centres, among others. Unfair practices in pharmaceutical marketing has been rampant in India. These practices include promoting drugs and pharmaceutical products with false claims and misleading names, providing gifts and other incentives to doctors to write more prescriptions, sponsoring holiday trips and foreign tours under the guise of medical conferences etc.

OPPI (Organisation of Pharmaceutical Producers of India) had in an official representation to the department of pharmaceuticals last month suggested

the government to make its ethical marketing guideline statutory.

The government had come out with a guideline in this regard two years ago, but has not enforced it.

"We have asked the government to make its Uniform Code of Pharmaceutical Marketing Practices (UCPMP) statutory. This will help bring much-needed discipline into the market place and increase trust among patients," Ranjana Smetacek, director general of OPPI, said in an interview. "OPPI members adhere to our stringent ethics code, which includes guidelines on marketing," she claimed.

According to Dilip G. Shah, secretary general of IPA (Indian Pharmaceutical Alliance), the industry has proposed self-regulation as a primary measure to stop unfair practices in the trade.

"We have decided to formulate ethical committees or ombudsmen to receive complaints and initiate action against violators as part of the self regulation, and a statutory provision by the government can be considered if the self regulation fails," said Shah.

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