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DCGI Turns Down Puducherry Drug Firm's Application

Accuses GuruFcure of fabricating data while seeking nod for making seven combination drugs

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NEW DELHI

Puducherry-based drugmaker GuruFcure has come under the Drug Controller General of India's scanner for allegedly submitting fabricated data while seeking approval for manufacturing seven fixed dose combination drugs.

"The investigative team concluded that all the data submitted (by the contract manufacturer in case of the seven combination drugs) is fabricated and not authentic," the central drug regulator told the drugmaker while rejecting its application last week in a letter, which was reviewed by **ET**. GuruFcure did not respond to ET's email query.

As per the company's website, its clients include leading pharma companies such as Abbott, Alkem, Glenmark, Wockhardt, Unichem and Intas Pharma, among others. The contract manufacturer, which started operations in 2007, calls itself "one of the leading pharmaceutical formulation manufacturers in India". While ET did not independently verify GuruFcure's claims, a representative of Wockhardt and a Glenmark spokesperson said the two companies were "not currently associated with this firm".

GuruFcure had earlier this year sought the regulator's approval to make varying combinations of antibiotics Cefixime and Ofloxacin, Cefixime and Azithromycin, Cepfodoxime and Azithromycin, among other combination drugs. "It was observed that the documents may not be authentic," the drug regulator said in its notice sent to the company. After an investigation concluded that the data submitted was fudged, the regulator on May 14 asked it to explain its position. The company submitted its reply on May 27.

"After examining the reply, it is observed that you have not submitted any satisfactory reply and for most of the points you have given clarification as 'typographical error', which is not acceptable," the regulator's letter said.

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The Drug Controller General of India has been prodding drugmakers since January to submit safety and efficacy data for combination drugs with the central drug regulator. If manufacturers fail to do so, the sale of these drugs will be forbidden in the country, it has warned. The government renewed its efforts to phase out 'irrational' combination drugs this year after a parliamentary panel last year criticised the regulator for not acting on such potentially unsafe drugs flooding the market.

Regulatory.

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