

India's drug regulator serves show-cause notice to online pharmacies

Gives firms two days to respond to allegations that they flouted rules

Sohini Das | Mumbai February 10, 2023 Last Updated at 13:09 IST



The Drugs Controller General of India (DCGI) has asked online

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pharmacies to explain why action should not be taken against them for sale and distribution in contravention of the law.

The DCGI sent a notice on February 8 and gave the firms two days to respond, failing which it would take action without warning. Business Standard has reviewed a copy of the notice.

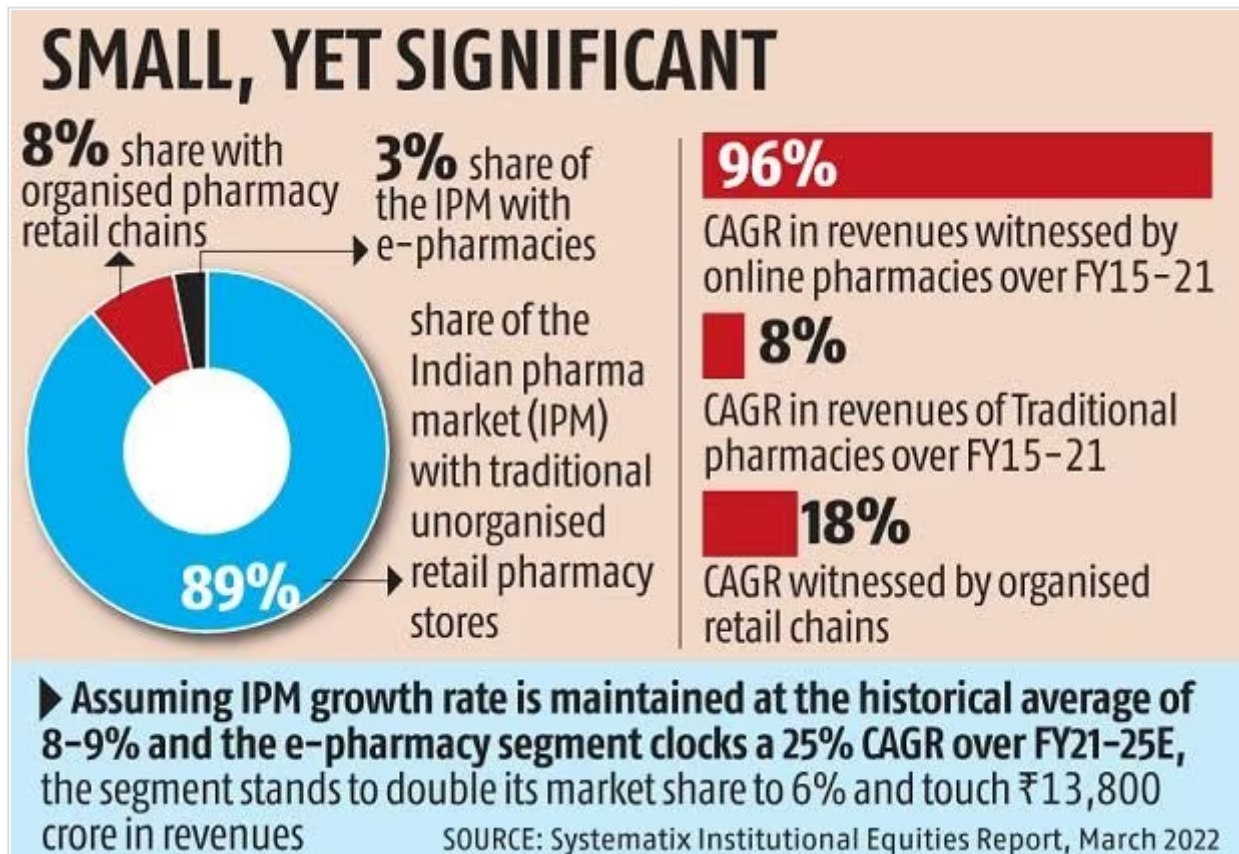
Sources said around 20 companies received the notice regarding alleged violation of the Drugs and Cosmetics Act, 1940. Sources in e-pharmacies said they were trying to understand what triggered the notice now, when a new Drugs and Cosmetics Act is awaited.

“The deadline to respond is tomorrow, and we will do so,” said the promoter of an online pharmacy.

Darren Punnen, leader, pharma and life sciences practice at Nishith Desai Associates, told Business Standard that the state food and drug administrations (FDAs) or governments were the licensing authorities for pharma manufacturing and retail.

The Centre looks after clinical trials.

“So, the CDSCO (Central Drugs Standard Control Organisation) has been issuing directions to state FDAs since 2019. The large online pharmacies are fulfilling the orders that they generate online from offline pharmacy stores (for which they have licence). If anyone is fulfilling orders directly from dark stores, then that can be in contravention of the provisions of the Drugs and Cosmetics Act. What can happen now is that the state agencies will check if players fulfil the conditions or if they are flouting the law and action can be taken accordingly,” Punnen explained.



V G Somani, Drugs Controller General of India, said in the notice that his office had received

representations about the sale of drugs online, including through mobile apps. Sale of drugs, as specified in the Act, is allowed only by a retail chemist on prescription from a registered physician and supplied under the supervision of a registered pharmacist.

Somani said according to section 18(c) of the Drugs and Cosmetics Act, manufacture for sale, distribution or stocking of drugs was prohibited except under and in accordance with the conditions of a licence issued for such purpose. Rule 62 stipulates that if a drug is sought to be sold or stocked for sale at more than one place, then a separate application is to be made to the licensing authority for grant of licence.

The DGCI notice quoted a December 2018 Delhi High Court order that restrained e-pharmacies from selling medicines without licence. Copies of that order were sent to all state drug controllers in May and November 2019, and then again in February 2023 for necessary action and compliance.

In January 2019, a division Bench of the Madras High Court had stayed an earlier single judge order banning online sale of drugs.

Punnen said: “Moreover, in the draft Drug, Medical Devices, and Cosmetics Bill, 2022, the Centre has made provisions for regulating e-pharmacies. Therefore, there is a possibility that the law may be amended to include selling drugs through the online channel.”

Retail chemists

Online pharmacies have been criticised by retail chemists in the past. On February 8, the All India Organisation of Chemists and Druggists (AIOCD) met Union Health Minister Mansukh Mandaviya in this

regard. AIOCD president JS Shinde said “predatory pricing” and “illegal activities” by e-pharmacies had affected the livelihood of 1.2 million of retail chemists.

Shinde added, “Secondly, online apps provided easy access to narcotic drugs, pregnancy termination kits, antibiotics, sedatives.” He said with interstate supply of drugs direct to patients, it became very difficult for state FDAs to track this.

A senior executive of an online pharmacy said on grounds of anonymity that the government had published the draft rules inviting comments from stakeholders for necessary amendments to the D&C Rules, 1945, for incorporating provisions relating to the regulation of sale and distribution of drugs through e-pharmacies. “What we know is that the Centre has asked the AIOCD to wait for the new Drugs and Cosmetics Act,” said the person.

He added that the DGCI notice was surprising because the health ministry last week spoke in Parliament about the draft rules. Bharti Praveen Pawar, minister of state for health, had said on February 3: “In order to regulate the online sale of medicines comprehensively, the Government of India has published draft rules for inviting comments from public/stakeholders for amendment to the Drugs and Cosmetics Rules, 1945, for incorporating provisions relating to regulation of sale and distribution of drugs through e-pharmacy. The draft rules contain provisions for registration of e-pharmacy, periodic inspection of e-pharmacy, procedure for distribution or sale of drugs through e-pharmacy, prohibition of advertisement of drugs through e-pharmacy, complaint redressal mechanism, monitoring of e-pharmacy, etc.”