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New rules open door for firms to exit price-controlled drugs

OUR BUREAU
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Pharmaceutical companies making essential drugs now have an easier option to discontinue producing those medicines whose prices are controlled. The Government has circulated a note on internal guidelines that eases the process of allowing companies to stop manufacturing scheduled formulations.

Unhappy with the National Pharmaceutical Pricing Authority's (NPPA's) constant review and increasing the number of drugs under the essential medicines list, pharma companies have been wanting to stop manufacturing such formulations.

The drugs under price control are meant for treating diseases such as tuberculosis, infections, heart diseases and epilepsy.

The exit option was available earlier too, but the companies had to inform the Government and file an application six months in advance. Under the fresh guidelines issued by the NPPA, companies will be allowed to discontinue manufacturing these medicines with a no-objection certificate from the NPPA, without any regulatory delays.

Now, the Government has decided to immediately allow a company to stop producing a drug, where it has less than one per cent market share and where more than 10 companies manufacture the drug.

Depending on the market share of the company applying for discontinuation of a drug and the number of players manufacturing the medicine, a no-objection certificate would be given by NPPA with stipulations, such as immediate discontinuation and supplying for six to 12 months since application is filed.

However, where there are fewer than five companies manufacturing a drug and the company holds more than five per cent market share (of the drug), the authority would need to grant approval before "no objection" is granted.

A Lupin spokesperson said that on first look, the move by the Government appeared to be good for the industry.

Registration process

Further, the Authority has also sent a notice to all drug makers to register with the Integrated Pharmaceutical Database Management System, under which they have to furnish reports on production, import, sale and price to retailer (pre-revised and revised) in respect of scheduled formulations and price list for both scheduled and non-scheduled formulations.

The Government needs this data to fix prices and monitor production and availability of scheduled formulations.

These guidelines will come as a respite for the manufacturers who, under the aegis of their association, had approached the Delhi High Court seeking intervention on the random decisions being taken by the NPPA on pricing. The companies stated that this (control price) would make production of essential medicines unviable in the country and compelled them to consider exiting.

The Government, under the Drugs (Price Control) Order, can fix the prices of scheduled formulations, which are used to manufacture medicines under the Essential Medicines List.

The controlled regime, under which more than 348 bulk drugs come under price control, has resulted in a legal battle between the Government and the pharma industry. This prompted the Delhi High Court to ask the Government and the pharma industry to resolve the issue, on Thursday.