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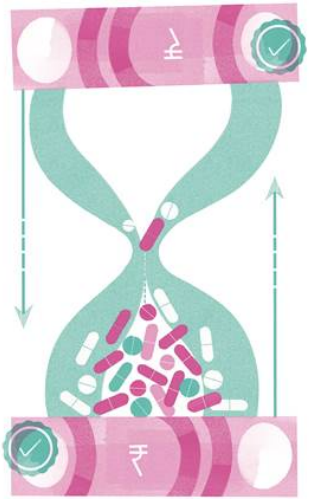
Easing licence extension for drug makers, sellers

The Central Drugs Standard Control Organisation has proposed charging a licence retention fee from drug manufacturers and chemists instead of the current renewal process; the fee for medical devices is expected to be in the range of `100-50,000.

Written by **Deepak Patel** | Published: June 23, 2017 1:46:23 am



According to the proposal, if a company or chemist does not pay this fee within the due date, the licence would be deemed as cancelled. (Illustration: C R Sasikumar)

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In a push for greater ease of doing business in the country, the Central Drugs Standard Control Organisation (CDSCO) has proposed to make it mandatory for pharmaceutical

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companies and chemists to periodically pay a licence retention fee instead of the current ambiguous practice of renewal of licences. According to the proposal, if a company or chemist does not pay this fee within the due date, the licence would be deemed as cancelled.

The central drug controller believes that once this provision is incorporated in the Drugs and Cosmetics Rules, 1945, it would be a part of "rationalising the grant of licences for manufacture or sale of drugs", as the licences of companies and chemists "who are not carrying on the business for a long time will stand cancelled".

BJP Lok Sabha MP Sakshi Maharaj had written a letter to Prime Minister Narendra Modi on January 30 asking him to ease the process of issuing licences for retail and wholesale medical stores. On March 1, the Prime Minister's Office forwarded this letter to the health ministry asking it to take appropriate action. On March 17, the health ministry asked G N Singh, Drugs Controller General of India (DCGI) — who heads the CDSCO — to give "requisite comments/inputs" as soon as possible.

On March 30, the office of DCGI responded with a note to the health ministry: "The Drugs and Cosmetics Rules, 1945, are being amended in consultation with the Drugs Technical Advisory Board (DTAB) for rationalising the grant of licences for manufacture or sale of drugs. It is proposed to provide that if the licensee fails to pay the licence retention fee on or before the due date or with late fee up to six months, the licence shall be deemed to have been cancelled." The office of DCGI further added: "Once the above provision is incorporated, the licensees who are not carrying on the business for a long time will stand cancelled." A licence for manufacture or for sale of a drug or cosmetic is generally valid for a period of five years — except in the case of ayurvedic drugs, unani drugs, etc — and has to be renewed thereafter.

In his letter to the Prime Minister, Sakshi Maharaj stated: "As you know, the process of obtaining a licence for a wholesale or retail medical store is exceedingly difficult and economically exploitative. The officials are taking bribes, leading to increase in corruption. Due to this, no new licences are being issued. People with old licences have shut down their businesses for various reasons. Due to this, people are getting affected. Therefore, I request you to take adequate steps to simplify the procedure of obtaining licences and cancel the licences of those who are not doing medical business for a long time."

While the concept of the 'license retention fee' is still under contemplation in the case of drug companies and chemists, it has been incorporated in the Medical Devices Rules, 2017, which will come into effect from January 2018. "Under this system (of retention fee), all licences are granted in perpetuity unless cancelled by the regulator, subject to payment of a licence retention fee after specified periods. In the case of medical devices, a licence retention fee would have to be paid after every five years from date of issue," said Ashish Prasad, partner, Economic Laws Practice.


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According to the Medical Devices Rules, 2017, the manufacturing licence retention fee of four different classes — Class A to Class D — of medical devices would range from Rs 100 to Rs 50,000. Import licence retention fee of the these four class of devices would range from $10 to $3,000 depending on the subject of licence.

According to Prasad, having licences issued in perpetuity will reduce much of the paperwork and time consumed to process renewal applications. Nevertheless, he added: “It appears to be a futuristic proposal targeted at removal of systemic road blocks to doing business in India. However, this would also call for a vigilant regulator and periodic inspections to ensure that manufacturing facilities, storage facilities, etc, are as per conditions of licence/approvals, etc. In the present regime, these periodic checks are expected to take place at least once in 5 years when the licences are renewed.”

To promote ease of doing business in the country, the CDSCO had on October 6, 2016, stated its intention to scrap the policy of periodic licence renewal for pharmaceutical companies and chemists. In India, a chemist needs a specific licence to sell a particular class of drugs. For example, licence in Form 20 is issued for the sale of allopathic drugs by retail other than those specified in Schedule C, C(1) and X. Similarly, licence in Form 20-C is issued for sale of homoeopathic medicines by retail.

As per the Centre, once the provision of licence retention fee is incorporated in drug rules, the licences of the companies or persons who are not carrying on the business for a long time will stand cancelled. The central government believes that it would help in ease of doing business. “Cancellation of licences in case the licensee has not been carrying on business will ensure streamlining of the data base of the regulator as we go forward,” Prasad said.

However, he added that introduction of system of licence retention fee by itself might not serve the purpose and will need to be accompanied by rules regarding reporting of closure of business. “This aspect can only be commented upon once the amended rules are notified,” he said.

For example, in the case of medical devices, as per Rule 26(xii) of the Medical Devices Rules 2017, if a licensed manufacturer has stopped manufacturing activity or closed the manufacturing site for a period of 30 days or more, it is obligated to inform the appropriate licensing authority (which is generally the state licensing authority). The health ministry and the CDSCO would have to form similar rules for pharmaceutical companies as well as chemists so as to fully take the benefits of this new provision of licence retention fee.

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