

Drug cos face five-fold hike in regulatory fees

Govt's Proposal May Not Lead To Price Rise

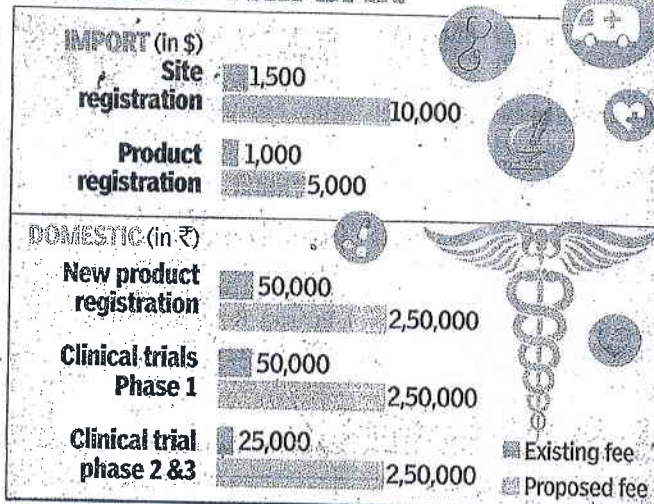
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New Delhi: Pharmaceutical companies may have to shell out more to do business in India. The government has proposed over five-fold hike in regulatory fees for testing, manufacturing and selling medicines in the country, a move that is likely to impact both domestic as well as multinational pharmaceutical companies operating here.

The health ministry has proposed to increase site registration fee for importing medicines to \$10,000 from \$1,500. The fees for registration of such imported pharmaceutical products is likely to go up to \$5,000 from \$1,000. The government has proposed a steep hike even in case of locally manufactured medicines. For any new product registration, companies may have to pay a fee as high as Rs 2,50,000 as compared to Rs 50,000 now.

While the proposal has met with a strong opposition from drug makers facing pricing pressures in India, the move may not impact consumers as medicine prices are largely regulated in the country. On the other hand, some believe consumers may benefit from the move as a higher fee is likely to result in better regulatory checks and efficient processes. Apart from pro-

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duct and site registration, the government has also proposed to increase fees for conducting clinical trials and for securing as well as renewal of license for stocking, exporting and even distributing medicines.

Once approved, the amendments in the fee structures will be part of the Drugs and Cosmetics Rules, 1945. The government and the regulator believe that fee hikes are much required and were long pending. "The pharmaceutical industry is growing with steep increase in revenue year after year. To tackle the increasing application load efficiently we need

funds and this has to be generated from the industry," a senior official said. He added India is still charging less than what companies have to pay abroad.

Internationally, governments would often subscribe to a fee hike to upgrade its regulatory agencies and processes. The US Food and Drug Administration (US FDA), considered one of the stringent drug regulators, had also imposed significant hike in product registrations, approvals and even on site inspections mainly for generics manufactured outside America when number of such filings increased a few years ago.

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