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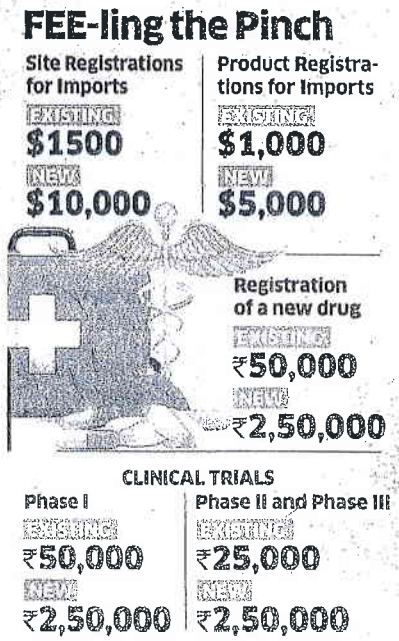
Steep Fee Hike Proposed for Drugs Licences, Registration, Manufacture



Centre feels circumstances make it necessary to make rules sans consulting Drugs Technical Advisory Board

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Mumbai: Drug makers may have to shell out significantly higher fees for a whole set of regulatory submissions in India in the New Year. The Ministry of Health and Family Welfare has proposed multi-fold fee increases for product registrations, manufacturing and product licences and clinical trials.

A December 29 gazette notification said the Central government is of the opinion that circumstances have arisen that render it necessary to make the rules without consulting the Drugs Technical Advisory Board, which advises it on important policy decisions. The process of consultations with the board, as per provisions, will be followed within six months from date of publication of rules.

The increase proposed in the new rules for site registrations for importing drugs is more than six-fold to $10,000 from $1,500. The charge for product registrations will jump to $5,000 from $1,000.

Fees proposed for local manufacturing and loan licence will jump more than eight-fold to ₹50,000 from ₹6,000. The charge for site inspections will increase 10-fold to ₹15,000. Fees for a licence to import drugs will be ₹10,000 from ₹1,000 currently. For registering a new drug, fees proposed will increase five-fold to ₹250,000. Clinical trials, the process of testing new drugs, will become more expensive.

Industry experts are divided over the proposed changes in the fee structure. While a senior executive from a European drug company said the existing rates had been low compared with markets such as China, an official from a large clinical research organisation said the sharp increase is not in line with the "ease of doing business" plank of the Indian government.

The notification has left some wiggle room for debate and called for any objections from interested parties.

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