

# Pharma units face heat for skirting mfg norms

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Pharmaceutical companies, which have failed to meet the July 1 deadline to comply with Schedule M, that deals with good manufacturing practices, of the Drugs & Cosmetics Act, will find the going tough.

The Drug Controller General of India (DGCI) has alerted state drug authorities to put units, which have shut down recently, under a special watch, fearing that they may continue production on the sly.

The original deadline for the implementation of Schedule M, aimed at improving manufacturing practices on the parameters of land area, equipment, storage, master formula records, and manufacturing records, was set

for 2002. Thereafter, the government extended the deadline thrice in the face of resistance by units represented by the Indian Drug Manufacturers Association and the Confederation of Indian Pharmaceutical Industry.

This has given rise to fears that as many as 2,000 units may be left with no option but to shut shop.

This is, however, being looked upon as just the cost of transition to better practices.

RAMashelkar, director general of Council for Scientific and Industrial Research, who headed the committee on spurious drugs, calls it "inevitable and essential rationalisation," which has to come about as the country adopts standardised modes of manufacturing.

Citing the example of Chi-

na, he said: "There are going to be costs which will be borne by small and medium enterprises." Ashwini Kumar, the DGCI, calls this the "normal course of economic flux in a transitory period".

According to D G Shah, secretary general of Indian Pharmaceutical Alliance, those companies which can't comply with Schedule M have no business to be in the market as quality standards cannot be compromised when lives are at stake. Both Mashelkar and Kumar acknowledge that some units may simply go underground.

Mashelkar, however, believes that the government should help these small companies in their rehabilitation.

There is also talks of a fund being constituted to bail out these out.