

DCGI to notify guidelines attached to Spurious Drugs Act to curb harassment of drug units

Thursday, October 22, 2009 08:00 IST

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In a bid to curb the possible misuse of powers by drug inspectors under the newly amended Drugs & Cosmetics Act, the Drug Controller General of India has started initiatives to notify the guidelines attached to the Bill to avoid unnecessary harassment to genuine drug manufacturers by the drug inspectors.

DCGI Dr Surinder Singh said that his office has already identified the appropriate provisions in the Drugs and Cosmetics Act under which the guidelines will be made binding on the drug inspectors. The sweeping powers given to the drug inspectors in the amended Act has been a major concern of the industry.

What has annoyed the industry more is the fact that contrary to the health ministry's earlier assurance to the industry to make the guidelines mandatory and legally binding, the ministry did not keep its words as legal experts in the pharma field are of the opinion that the new guidelines issued along with the notification by the ministry is not binding on the drug authorities, just like the 1993 DCC guidelines.

With the guidelines non-binding on the drug inspectors, there was fear among the industry that the genuine drug manufacturers will also be harassed by the drug authorities. The industry fears that if the Act is implemented in its present form, it will have far reaching consequences as there are several provisions in the Act which can be misinterpreted and misused by the authorities. The industry fears that some of the provisions in the Act are so anti-industry that there will be no option for the genuine drug manufacturers but to leave the industry.

Since getting bail is almost impossible and guidelines not legally binding, the fear of prosecution will always hang as the proverbial Sword of Damocles over the head of the drug manufacturers. Major producers of spurious drugs are clandestine operators who ought to use labels of licensed manufacturers. When such drugs enter the chain, the manufacturer whose labels are misused shall face prosecution despite being innocent.

The Drugs and Cosmetics (Amendment) Bill was passed by Parliament in October last year and it received President's assent in December last year. The Union Health Ministry on August 10 this year had notified the Drugs Act Amendment Bill, enhancing the punishment to 10 years imprisonment and a fine of Rs 10 lakh for production and sale of spurious drugs. Under the new amendment in the Act, production and sale of spurious drug is a non-bailable offence.

Source-Pharmabiz

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