



PHARMACEUTICALS EXPORT PROMOTION COUNCIL

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Health ministry to issue direction to states u/s 33P of D&C Act on Spurious Drugs Act Guidelines

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Ramesh Shankar, Mumbai

Direct link to the News/Story:-

<http://www.pharmabiz.com/article/detnews.asp?articleid=57246§ionid=>

The tussle between the Union health ministry and the pharma industry over the notification of the Guidelines attached to the Spurious Drugs Act to allay apprehensions about the various provisions of the Act will end soon as the ministry will soon issue directions to the state drug authorities under section 33P of the Drugs & Cosmetics Act.

Union Health Minister Ghulam Nabi Azad's announcement in this regard in Mumbai after meeting the captains of the industry will finally put at rest the dilly-dallying of the senior health ministry officials on the issue. In fact, irritated over the attitude of the senior officials of the ministry, who have been dragging feet on the issue, the industry was seriously contemplating to move Supreme Court to curb possible harassment of genuine drug manufacturers by the drug inspectors by misinterpreting some of the provisions in the Act.

Sources in the ministry said that once the ministry issues directions under section 33P of the D&C Act, the state drug authorities have to follow the directive before executing the various provisions of the Spurious Drugs Act. Though the ministry had earlier circulated the Guidelines attached to the Act to all the states, the states have not been following it as it was not mandatory for the officials to pay heed to the Guidelines.

Now that the ministry has decided to issue directions under section 33P, the state drug authorities have to follow the Guidelines before executing various provisions of the Spurious Drugs Act which, apart from making production and sale of spurious drugs a non-bailable offence, enhanced the punishment to 10 years imprisonment and a fine of Rs.10 lakh.

The Drugs and Cosmetics (Amendment) Bill, better known as Spurious Drugs Act, was passed by Parliament in October 2008 and it received President's assent in December same year. The Bill, was notified on August 10, 2009, by the union health ministry.

Ever since, there was outcry from the industry over the sweeping powers given to the drug inspectors in the amended Act. It feared that the genuine drug manufacturers will also be harassed by the drug authorities. The industry feared 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 drug authorities.

As the industry expressed its concern, the union health ministry had come up with a set of guidelines and senior health ministry officials had given an assurance to the industry that it will make the guidelines mandatory and legally binding to ensure that genuine manufacturers are not harassed by the drug authorities.

But, even after an year since the ministry has notified the Bill, it is yet to notify the guidelines.