



## PHARMACEUTICALS EXPORT PROMOTION COUNCIL

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### **Industry objects to RITES' move to make WHO-GMP mandatory for taking part in tenders**

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Direct link to the News/Story:- <http://www.pharmabiz.com/article/detnews.asp?articleid=56117&sectionid=>

In apparent violation of earlier orders of the DCGI and Jharkhand High Court, some drug procurement agencies like RITES and some state governments have made it mandatory for the pharma companies to have WHO-GMP certificate for participating in their tenders for procuring drugs for supplying them for the government-run hospitals in the country. The industry has termed the move as 'blatant violation of directives of DCGI and prevalent law'.

After enhancing the turnover criterion to astronomical levels from Rs 3 crore to Rs 35-50 crore, the latest decision of RITES and some state governments will virtually disqualify the small pharma companies from participating in the government tenders.

According to industry sources, RITES in its latest tender notification has made it a precondition that the drug companies which possess the WHO-GMP Certification can only participate in its tenders for procuring drugs for supplying them for different central government hospitals. The central government had some time back appointed RITES as the agency for procuring drugs at competitive rates from the private drug manufacturers to supply the them in the government-run CGHS dispensaries and other hospitals.

Apart from RITES, some state governments like Jharkhand have also made it mandatory to have WHO-GMP Certification for participating in the government tenders for procuring drugs for the state-government run hospitals.

Industry has termed the action of RITES and some state government as illegal. Quoting the drug controller general of India's (DCGI) letter dated March 1, 2004, the industry said that it has been made clear to State Licensing Authorities that WHO-GMP Certificates and COPP shall be issued only in case of export of drug and not for supplying drugs in India.

Besides, in the judgment of Uttaranchal High Court titled Poddar Pharmaceuticals v/s State of Uttaranchal & others, it has been made clear that WHO-GMP is not required for local purchases within the country and it is required only for exports.

Meanwhile, industry sources regretted that the vested interests have managed to get the stipulation inserted in the tenders of RITES to eliminate SMEs in blatant violation of directives of DCGI and prevalent law.