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DCGI to move Supreme Court on CoPP issue

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The ongoing battle between the Drug Controller General of India (DCGI) and the industry over the issuance of CoPP is poised to take a turn for the worse as the DCGI is contemplating to move Supreme Court to find an early solution to the issue. Presently, four stay orders on the CoPP issue are pending in the Karnataka and Madras High Courts for several months. The Madras High Court had on January 18 adjourned the matter for the seventh time to January 28.

According to sources, Union health minister Ghulam Nabi Azad, who is also annoyed over the inordinate delay in finding an early solution to the issue, has given his in-principle approval to move Supreme Court. Once the official procedures are completed, the DCGI office will move the Supreme Court seeking early solution to the issue, which has been pending since October 13 last year when the Madras High Court granted stay on the DCGI order on CoPP. As per the DCGI order issued on September 1 last year, the DCGI wanted to centralise the issuance of CoPP from October 1, 2009 which was until then issued by the state drug controllers.

The DCGI move in this regard comes in the wake of the thinking in the union health ministry that the CoPP issue should not go the FDC issue way as even after several years, the FDC issue is still pending in the Madras High Court for a final decision. For the early vacation of the stay orders on CoPP, the DCGI office had submitted a foolproof document to the court, plugging all legal loopholes. Even though the stay orders were granted for a period of 8 weeks, the DCGI office wanted to vacate the stay much before that. But, even after all his efforts, the court kept on adjourned the matter prompting the health ministry to move Supreme Court.

Apart from getting an early solution, another reason for moving the Supreme Court is that once the issue reaches the Supreme Court, all the cases related to the issue pending in other High Courts can be transferred to the Supreme Court so that the DCGI office does not have to attend the cases in different High Courts which the DCGI office finds very cumbersome. Presently, three stay orders on the issue are pending in Madras High Court and one stay order is pending in the Karnataka High Court.

Even as the industry and the DCGI have locked horns on the issue, both have their own justifications to support their views.

DCGI Dr Surinder Singh was on record saying that his action on centralisation of CoPP was aimed at strengthening the regulatory framework in India to instil confidence among the world trading community to give a boost to the offshore commerce. He had said that the country's reputation was at stake due to the multiple authorities in issuing the COPP which is an important document as far as international commerce

is concerned. His action was also based on a WHO letter in which the world health body has found fault with the way the COPP was issued in India.

Meanwhile, the industry is opposing the move on the apprehension that there will be avoidable delays in issuing the certificate. Its apprehension stems from the fact that the DCGI office does not have the infrastructure to dispose of the application for WHO-GMP certificates expeditiously.