

Ban on FDCs: HC asks if legitimacy of approval be considered

PTI | Mar 30, 2016, 06.35 PM IST

New Delhi, Mar 30 () Delhi High Court today asked the Centre whether the legitimacy of approvals held by the pharma companies, challenging government's decision to ban 344 fixed drug combinations (FDCs), needs to be considered as this was not given as a reason to ban these medicines. "You have not prohibited the drugs/FDCs on the ground of legitimacy of their approval. So do we need to go into it? Can we proceed under the premise that approval is not an issue," Justice Rajiv Sahai Endlaw asked the government.

Additional Solicitor General (ASG) Sanjay Jain, appearing for the Centre, said the drugs were banned as they had no therapeutic justification and not on the ground of approval but most of these firms did not hold a valid licence to make the FDCs, which were banned by its March 10 notification. However, senior advocate Colin Gonsalves, appearing for All India Drug Action Network (AIDAN), contended that the issue of approval has to be gone into.

Senior advocate Kapil Sibal, appearing for various drug companies including Pfizer, said they were not making medicines without approval. "They (government) are free to take action against us if we do not have approval," he said. Sibal argued that the legitimacy of approval was the reason for setting up of an expert committee and claimed that this panel had not applied its mind or done its "homework" while recommending a ban on these FDCs. As an example of alleged non-application of mind, he said that Pirmal's Saridon drug was approved in 1982 and as per the government, pre-1988 drugs do not require fresh approval from the Drugs Controller General of India (DCGI). However, the expert panel banned it, he added.

The court was hearing over 150 petitions by pharma majors like Pfizer, Glenmark, Procter and Gamble (P&G) and Cipla, who have challenged the government's March 10 decision which has been stayed by the judge in each case filed before it since March 14. After hearing the submissions of Sibal, the court listed the matter tomorrow for further arguments. It also said it would compile the doubts it has in the form of an order and send it to both sides for their perusal and response. (More) HMP ABA ARC

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