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## Delhi HC quashes government ban on fixed dose combination drugs

The verdict is a major relief for the pharmaceutical sector. In a major relief to the pharmaceutical sector, the Delhi high court on Thursday overturned a government ban on more than 300 fixed dose combination (FDC) drugs.

Justice Rajiv Sahai Endlaw allowed the petitions of the drug companies, in effect setting aside the government's March notification.

The government banned 344 FDC drugs on 10 March, citing health risks and lack of therapeutic justification. An FDC is a cocktail of two or more active drug ingredients in a fixed ratio of doses.

The government is likely to challenge the order, additional solicitor general Sanjay Jain said.

Pharma companies were satisfied with the decision.

“We welcome the Hon’ble Delhi High Court’s order. Pfizer stands by the safety and efficacy of current Corex Cough Syrup formulation that has due approvals from Central and State regulators,” said a Pfizer company spokesperson.

Pfizer Ltd was the first to get a stay on the [ban of its Corex cough syrup](#).

An Abbott spokesperson said, “The judgment provides thousands of patients continued access to Abbott’s doctor-prescribed products, which have the necessary regulatory approvals for manufacture, distribution and sale in India.”

The cases—filed by several drug companies and industry bodies in as many as 454 petitions—question the validity of the ban.

In its judgment, the court found that the government failed to consult statutory authorities like the Drug Testing Advisory Board and the Drugs Consultative Committee for the ban.

Endlaw clarified that the verdict did not decide on the issue of the FDC drugs being risky to consumers. It only found that proper procedure had not been followed for imposing the ban.

The court also recorded that the Central Drugs Standard Control Organisation was not a statutory authority.

During the hearings, the government maintained that the ban was in public interest as the combination drugs were not safe and had been banned in several other countries.

Some major firms involved in the case are: Pfizer, Wockhardt Ltd, Alkem Laboratories Ltd, Cipla Ltd, Sanofi India Ltd, Sun Pharmaceutical Industries Ltd. The major brands included in the ban were P&G's cold and cough drug Vicks Action 500 Extra, Piramal's Saridon, Reckitt's D Cold Total and Glenmark's Ascoril-C.

“Most companies were trying to bring in the banned drugs back into the market by using a different combination. This judgment is a relief for the industry but we expect it to be challenged in the Supreme Court by the government,” said an analyst, who did not wish to be named citing company policy.

Leena Menghaney, access campaign India co-ordinator at the non-profit Médecins Sans Frontières, however, said that the ruling was not good for public health or patient safety.

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