Government need not consult statutory board to ban combo drugs: Supreme Court

By *Samanwaya Rautray*, *Prabha Raghavan*, ET Bureau | Updated: Nov 16, 2017, 04.38 PM IST

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NEW DELHI: The Supreme Court on Wednesday said the central government need not consult the statutory board on drugs before banning any fixed-drug combinations, an observation that goes against a major legal plank of companies battling against a ban on 344 such products.

Fixed-dose combinations (FDCs) are cocktail drugs of two or more therapeutic ingredients packed in a single dose.

A central government notification banning the 344 fixed-dose combinations in 2016 was set aside by the Delhi High Court in December. The government had banned these combinations in public interest, claiming they were unsafe and "irrational".

The ban had hit several popular brands like Corex, Saridon, D'Cold Total and Vicks Action 500 Extra, prompting pharma companies to submit over 500 petitions at around 10 high courts, with Delhi receiving a sizeable chunk.

The government challenged these in the top court on the ground that the ban was necessary in public interest, prompting the top court to stay the order.

Pharma companies such as Glenmark NSE -0.60 %, Pfizer NSE -1.79 % and Procter & Gamble had contended that the principle of natural justice required some kind of hearing from stakeholders before the government can take a call on a technical subject like this one.

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Before prohibiting fixed-dose combination drugs, the government must consult the statutory bodies provided for in the Drugs and Cosmetics Act, the companies had argued before a bench of Justices RF Nariman and Sanjay Kishan Kaul.

“Otherwise the power would be unfettered, unlimited,” senior advocate Abhishek Manu Singhvi had said. “This cannot be done without consulting the stakeholders. Public safety, public risk can only be assessed on the basis of expert inputs.”

In the absence of an emergency, such a consultation should be made mandatory, he had argued.

Justice Nariman, however, said such consultations were not specified in Section 26A of the act, which defines the power of the Central government to regulate the manufacture and sale of drugs and cosmetics in public interest.

“If we hold otherwise, we will neither be reading the law up or down but reading in, which is legislating,” Nariman said. Justice Kaul also said the arguments would have been appealing had the subject matter been anything but drugs.

The court said it was with the government on this legal point. The companies will now likely argue the other legal points against the ban at the next hearing, scheduled for Dec 6.

"Arguments on December 6 will look at how many FDCs can be excluded from the ban and how many we are not able to justify entirely," a lawyer involved in the case told ET, speaking on the condition of anonymity.

The industry is positive about the court's decision to allow further arguments in this case.

“The judge is open to hearing a little bit from our side as well, which is positive," said RK Sanghavi of pharmaceutical lobby group Indian Drug Manufacturers Association.

The association on Wednesday submitted a list of around 175 FDCs out of the original list of 344 that it had determined were not only safe for consumption but needed for specific patients, he said.

This list excluded the FDCs approved before 1988 and those already approved by the Drug Controller General of India, he added.

"The judgment will definitely have an impact depending on how much commercials are at stake and more importantly on the patients' dependency on such FDCs, especially in cases of chronic diseases," said Ashish Prasad, partner at Economic Laws Practice.

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By *Prabha Raghavan*, ET Bureau | Updated: Sep 02, 2018, 06.34 AM IST

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The impending ban had sent hospitals into a panic-buying mode.

NEW DELHI: The Delhi High Court has suspended the health ministry's restrictions on private companies making and selling lifesaving drug oxytocin for a month while it hears petitions opposing the move. The court will hear the case next on September 12, it said on Friday.

"This is an interim move for the court to provide enough room to hearing all the arguments in this case," a lawyer present in court said on condition of anonymity.

Oxytocin is a hormone drug used to induce labour in pregnant women and prevent post-partum bleeding. The curbs were aimed at preventing illegal supply and misuse of the drug in cattle.

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According to the court order, statutory bodies Drugs Technical Advisory Board and Drugs Consultative Committee raised concerns that emphasise that prohibition or restricted sale of oxytocin "would not be in order."

As many as 116 inspections to track illegal sales of oxytocin have resulted in prosecution in 12 instances in the past four years and the figures suggest that only two out of 112 licensed manufacturers have had their permits suspended, according to the order. The details of seizures conducted suggest that abuse of the drug is widespread only in regions including Bihar and West Bengal, Justices S Ravindra Bhat and AK Chawla said in the order.

"The materials disclosed to the court also show that when the discussion to restrict the domestic sale of oxytocin was taken in February 2018, KAPL, as a matter of fact, was not even licensed to manufacture the drug," they said, adding that the company was issued a licence in April 2018.

Mylan is one of the companies that has opposed the ministry's plan in court. Pfizer has stopped manufacturing the drug and planned to exhaust its inventory of the product within two months, ET reported on July 26.

ET had also reported then that the impending move had sent hospitals into a panic-buying mode. The size of the oxytocin market was about Rs 50 crore in the 12 months ended July 2018, with Pfizer capturing an over 40% share, according to pharmaceutical market research firm AIOCD PharmaTrac.

Patient activist group All India Drug Action Network has also filed a petition, which is being heard along with the pleas of Mylan subsidiary BGP Products Operations Gmbh and Neon Laboratories.

"KAPL's ability to single-handedly produce an emergency drug for the entire country and ensure the supply all over India while maintaining a cold chain… is untried and untested," AIDAN said in its petition, a copy of which ET has reviewed. "A slight disruption or problem in functioning of the supply chain would mean unnecessary maternal deaths."

Oxytocin is considered a lifesaving drug and is included in the National List of Essential Medicines of 2011 and 2015 as well as the WHO Model List of Essential Medicines.

About four women die every hour in India from complications developed during childbirth, with heavy blood loss from haemorrhaging being "a major factor," AIDAN said in the petition, citing data from the Registrar General of India.

ET's queries to Mylan, Neon Laboratories and AIDAN remained unanswered by press time on Friday.

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