Supreme Court asks drugs advisory body to decide fate of over 334 banned combination medicines

By *Prabha Raghavan*, ET Bureau | Updated: Dec 15, 2017, 12.31 PM IST

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FDCs are cocktail drugs that contain two or more therapeutic ingredients packed in a single dose.

NEW DELHI: The Supreme Court has asked the country's technical advisory body on drugs to decide on the fate of more than 300 combination medicines banned by the government between March 2016 and June 2017. The order is a potential relief to drug makers who have argued that the government did not consult statutory bodies provided for in the country's drug regulations before banning these drugs.

Companies can make and sell the 349 contested fixed dose combination drugs (FDCs) while Drugs Technical Advisory Board (DTAB) deliberates on the issue.

At the same time, the court also clarified that this order is specific to two of the government's ban notifications due to "peculiar facts" of the cases.

In an order dictated in open court on two government notifications banning these FDCs, a Supreme Court bench of Justices Rohinton Fali Nariman and Sanjay Kishan Kaul on Thursday said it was setting aside the ban on 15 such drugs which were manufactured in India before 1988.

However, if it chooses to, the government can carry out further inquiry on whether these drugs should continue to be marketed in the country, the court suggested.

For the remaining 334 FDCs, the court suggested that DTAB should decide whether the manufacture and sale of these drugs should be regulated, restricted or outright banned, and submit a report with its recommendations to the government within six months.

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The bench will pronounce its official judgment on Friday.

FDCs are cocktail drugs that contain two or more therapeutic ingredients packed in a single dose.

While 344 of the contested drugs are currently available in the market as the Delhi High Court in December last quashed the ban on them imposed in March last year, the other five FDCs banned in June, too, can now return to the market.

The Supreme Court bench said DTAB or a sub-committee it sets up should hear arguments by the drug industry as well as patient group All India Drug Action Network (AIDAN), which is in favour of the ban notifications, before preparing its report.

The government is expected to carefully consider this report, “apply its mind” and accordingly either maintain or modify its ban notifications, according to it.

The Kokate committee — the government’s expert committee that had studied the FDCs and declared them “irrational” — was not clear as to the reasoning behind its decision, it observed.

The top court last month said the government does not have to consult statutory bodies like DTAB before banning FDCs as such consultations were not specified in Section 26A of the Drugs and Cosmetics Act. The government had used Section 26A, which defines its power to regulate the manufacture and sale of drugs "in public interest", to ban these drugs last year on a separate expert committee's recommendation.

“The judgment means that the government need not mandatorily consult DTAB to prohibit the manufacture and sale of FDCs it finds irrational and can use expert committees like the Kokate committee,” said S Srinivasan, a member of AIDAN. “Earlier, the Delhi High Court had quashed the ban only on the reasoning that DTAB was not consulted, but now the government has been empowered to act fast,” he said. “The only drawback is that six months seems too short a deadline to achieve all this,” he added.

AIDAN’s counsel Colin Gonsalves told the court on Thursday that there are 40,000 contested and debated FDCs in India, while any well-regulated country allows 500 FDCs at most.

Lawyers representing drug makers said the decision is a victory for the industry.

“The court has referred the matter for a fresh look to decide if the drugs require to be banned under Section 26A of the Drugs & Cosmetics Act,” said Ashish Prasad, partner at Economic Laws Practice, who represented Indian Drug Manufacturers Association (IDMA), Federation of Pharma Entrepreneurs (FOPE) and Confederation of Indian Pharmaceutical Industries (CIPI) during the proceedings.

Archana Sahadeva, associate partner at Singh & Singh Law Firm, who represented drug makers such as Cipla, MacLeods, Alembic and Microlabs, said, “This means that the process will now be more transparent.”

The 300 plus contested drugs include popular brands such as Corex, Phensedyl, D’Cold Total, Vicks Action 500 Extra and Saridon.

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ET Bureau | Oct 23, 2018, 07.54 AM IST

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The court is expected to hear the PIL this week.

High Court seeking a directive to restrict over-the-counter sale of antibiotics in India, the world's "largest consumer of antibiotics".

The petition followed investigation by an activist who found that antibiotics under 'restricted use' were freely available over the counter across pharmacies in India.

The PIL pointed to the United Nations high-level meeting on antimicrobial resistance and said a UN declaration had asked countries to come up with an action plan to curb the misuse of antibiotics by 2018.

"That the pressure is on India, the world's largest consumer of antibiotics and where carelessness in antibiotic use and environmental antibiotic pollution has been documented," the petition said.

The court is expected to hear the PIL this week.

Antibiotic drugs are part of a nearly Rs 17,000 crore business in India, growing at 5-6% annually.

India is one of the highest consumers of antibiotics. These drugs are also used rampantly in agriculture, specifically for poultry and livestock.

Read more on PIL Bombay HC High Court Restricted Use India Antibiotics

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Are companies bribing doctors to push vaccine combos?

By *Rema Nagarajan*, TNN | Oct 22, 2018, 10.44 AM IST

Most firms dismiss this as a practice of "fixed margins" on MRP prevalent across pharma and vaccine industries or as "business terms" offered to customers.

A vaccine against five diseases costs Rs 2,800. Add one for a sixth disease, Hepatitis B, to this combination and the price jumps to Rs 3,900 though the Hepatitis B vaccine by itself is just Rs 60. Another vaccine against five diseases including Hepatitis B costs Rs 382, but the addition of a polio vaccine pushes the price up to Rs 2,392 though the standalone injectable polio vaccine (IPV) costs just about Rs 400 in the open market.

Paediatricians question these huge price increases with the addition of just one more vaccine. Vaccine companies' spokespersons say it is because adding a component makes the manufacturing process more complex.

What makes this a real problem is that the standalone IPV is not available any more, forcing paediatricians to buy the combination vaccine. Earlier, two brands of standalone IPV were available in India, Erapol from Biological Evans and Imovax from Sanofi, for Rs 400. Sanofi told TOI IPV was not available in the open market because of a global shortage. Sanofi supplies the standalone IPV to the immunisation programme at Rs 172.

A dose of Easy Five vaccine from Panacea Biotec, against diphtheria, pertussis, tetanus, pneumonia and hepatitis, costs Rs 382 in the open market as it's under price control. However, Easy Six, which includes all vaccines in Easy Five plus IPV, costs parents Rs 2,392, Rs 1,610 more than when the two are given separately.

While companies claim the extra cost is due to the complexity of manufacturing combination vaccines, whether it is Pentaxim or Hexaxim, the maximum retail price leaves

diseases at Rs 2,392, over Rs 475 goes as incentive to doctors or hospitals. Most firms dismiss this as a practice of "fixed margins" on MRP prevalent across pharma and vaccine industries or as "business terms" offered to customers. But of course, it's the person who decides which product to choose – the doctor or hospital -- who gets to pocket the incentive, while the baby's parents pay the MRP.

(This article was originally published in The Times of India)

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Zydus Cadila gets USFDA nod for generic gout attacks drug

The drug is used to prevent or treat attacks of gout, a condition caused by high uric acid levels in the blood. The medication is also used to treat familial Mediterranean fever.

NEW DELHI: Drug firm Zydus Cadila Thursday said it has received a tentative nod to market generic Colchicine tablets used for prevention and treatment of gout attacks in US market.

The company has received the tentative approval from the United States Food and Drug Administration (USFDA) to market Colchicine tablets USP in the strength of 0.6 mg, Zydus Cadila said in a statement.

The product is the generic version of Colcyrs tablets in the same strength, it added.

The tablets, "will be manufactured at the group's formulations manufacturing facility at SEZ, Ahmedabad," it said.

The drug is used to prevent or treat attacks of gout, a condition caused by high uric acid levels in the blood. The medication is also used to treat familial Mediterranean fever.

The group now has 223 approvals and has so far filed over 330 abbreviated new drug applications (ANDAs) since the commencement of its filing process, Zydus Cadila said.

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DCGI asks company to recall Ozurdex Intravitreal implants

PTI | Oct 16, 2018, 07.43 PM IST

The silicone sleeve is an intrinsic part of the Ozurdex product and the particle is not an external contaminant, it said.

The Drug Controller General of India (DCGI) has asked a pharmaceutical company to recall one of its products, Ozurdex Intravitreal Implant, a steroid eye implant for macular edema, after the company admitted that a silicone particle has been detected in it. During a routine manufacturing inspection, a silicone particle, approximately 300 microns in diameter, was observed in dispensed Ozurdex implants, a statement by the Allergan India Private Limited said.

The silicone particle has been confirmed to originate from the needle sleeve.

The silicone sleeve is an intrinsic part of the Ozurdex product and the particle is not an external contaminant, it said.

Batches of Ozurdex already distributed in India are affected by this defect. Generally, most batches have 2 to 4 per cent defective units, but defect rates as high as 22 per cent have been reported, the company statement said.

"Ozurdex batches known to be affected are being recalled from the Indian market. New stocks of Ozurdex that are reliably known to be free of this defect will be made available in India and Allergan will provide an update when new stocks will be available for each market," it said.

Until unaffected product is available, clinicians are advised to consider alternative treatments.

Allergan has identified a corrective action that eliminates creation of the particle and is working quickly to implement this action prior to releasing any further product in agreement

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A separate communication is also being sent to hospitals providing details of the recall process, it added.

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