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

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.

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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Glenmark inks licensing pact for generic Tiotropium Bromide dry powder inhaler in Western Europe

PTI | Aug 29, 2018, 11.21 AM IST

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NEW DELHI: Glenmark Pharmaceuticals Europe has entered into a strategic, exclusive licensing agreement for marketing generic Tiotropium Bromide dry powder inhaler, used in the treatment of chronic obstructive

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Tiotropium Bromide DPI is a generic version of Boehringer Ingelheim's Spiriva Handihaler.

in the treatment of chronic obstructive pulmonary disease, in Western Europe.

Glenmark Pharmaceuticals EVP & Business Head of Europe and Latin America Achin Gupta said, respiratory is a core area of focus for Glenmark and this deal shows our commitment to increase product offerings within this segment.

"There is significant opportunity in the inhalers market and we believe that this deal will give further impetus to Glenmark's growth in Europe," he added.

This is the second inhalation product in-licensed by Glenmark for the European market after Fluticasone/Salmeterol dry powder inhaler, the company said.

Tiotropium Bromide DPI is a generic version of Boehringer Ingelheim's Spiriva Handihaler.

Quoting IQVIA data, Glenmark said Boehringer Ingelheim's Spiriva Handihaler recorded sales of USD 724 million in the European Union in the 12 month period ended March 2018.

Shares of Glenmark Pharma were trading 0.85 per cent higher at Rs 648.85 on BSE.

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Lupin gets USFDA nod to market its postherpetic neuralgia drug

PTI | Aug 28, 2018, 02.22 PM IST

Lupin's tablets are generic version of Pfizer Inc's Neurontin tablets in the same strengths.

NEW DELHI: Drug firm Lupin today said it has received approval from the US health regulator to market its generic Gabapentin tablets used for treatment of postherpetic neuralgia in the American market.

The company has received final approval to market its Gabapentin tablets USP in the strengths of 600 mg and 800 mg from the United States Food and Drug Administration (USFDA), Lupin said in a statement.

The company's tablets are generic version of Pfizer Inc's Neurontin tablets in the same strengths, it added.

As per the IQVIA MAT June 2018 data, Gabapentin tablets USP, 600 mg and 800 mg had annual sales of around USD 180.7 million in the US, Lupin said.

The product is "indicated for the treatment of postherpetic neuralgia in adults and adjunctive therapy in the treatment of partial onset seizures, with and without secondary generalisation, in adults and pediatric patients 3 years and older with epilepsy."

Shares of Lupin were today trading at Rs 910.75 per scrip on BSE, up 0.34 per cent from its previous close.

Read more on USFDA Lupin Gabapentin Tablets Postherpetic Neuralgia Seizures

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India's health ministry still 'deliberating' on findings on J&J's faulty hip implants, says JP Nadda

By *Prabha Raghavan*, ET Bureau | Aug 28, 2018, 09.42 AM IST

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T he health minister's statement on Monday suggest that the government may wait to take action in this matter.

NEW DELHI: The government is yet to release the findings of an expert committee that reportedly found US drug giant Johnson and Johnson guilty of concealing information related to faulty hip implants that have rendered several Indian patients with permanent disabilities. This is because the health ministry is currently still "deliberating" on the committee's report, said health minister JP Nadda during a media briefing on Monday.

The expert committee reportedly recommended that each affected patient

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receive compensation of Rs20 lakh and is said to have submitted its report in February this year. However, the findings of this committee and its recommendations have not been made public.

Meanwhile, officials close to the development have said that the health ministry has accepted the recommendations and is coordinating with states to set up committees to find any aggrieved patients that have not come forward to claim damages. These committees are expected to advertise for patients to approach them and, depending on physical and clinical data, the committee is expected to ascertain to what extent the hip implants have caused damage to the patient. Subsequently, a central committee is supposed to take these findings and suggest a compensation for the patient that J&J will have to pay up, officials earlier told ET.

Yet, the health minister's statement on Monday suggest that the government may wait to take action in this matter.

"We share your concerns, however we are still deliberating upon the matter," said Nadda in response to queries on why the report had not been made public and why no stringent action has been taken in this matter yet even though the committee's findings had been submitted six months ago.

J&J, through subsidiary DePuy Orthopaedics, had issued a global recall of the implant system, called ASR Hip System, in 2010 after it received "new information" from the UK National Joint Registry, a J&J spokesperson earlier said.

Reportedly over 4,500 patients in India had received this implant, and J&J is said to have reported over 100 serious adverse events to the Central Drugs Standard Control Organisation between 2014 and 2017.




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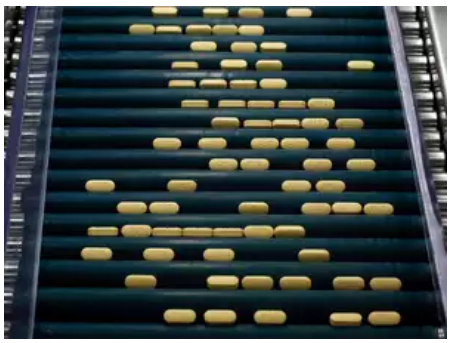
Lupin launches contraceptive drug in the US market

PTI | Aug 27, 2018, 01.45 PM IST



Lupin's product is a generic equivalent of Bayer's Beyazs tablets.

Drug maker Lupin today launched Drospirenone, Ethinyl Estradiol, Levomefolate Calcium tablets and Levomefolate Calcium tablets, used to prevent pregnancy, in the US market.

The company has launched the product in the US after having received approval from the US Food and Drug Administration (USFDA) earlier, Lupin said in a BSE filing.

Approval was granted in the strengths of 3 mg/ 0.02mg/ 0.451 mg and 0.451 mg.

Lupin's product is a generic equivalent of Bayer's Beyazs tablets.

Quoting IQVIA MAT June 2018 data, Lupin said Drospirenone, Ethinyl Estradiol and Levomefolate Calcium Tablets and Levomefolate Calcium Tablets had annual sales of approximately USD 80.8 million in the US.

Lupin shares were trading 0.38 per cent up at Rs 910.60 apiece on BSE.

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USFDA conducts inspection of Sun Pharma's Halol site: Sources

ET Bureau | Aug 27, 2018, 11.36 AM IST

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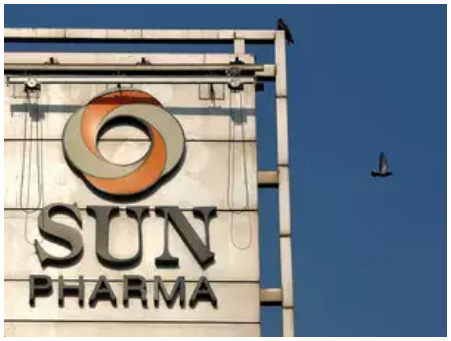

The nature of the inspection – whether it is a PAI (pre-approval inspection) or a GMP (good manufacturing practices) – could not be ascertained

The U S Food and Drug Administration (USFDA) is conducting an inspection at Sun Pharma's Halol facility in Gujarat. The site produces multiple dosage forms – from tablets to ointments to injectables – and was cleared by the US drug regulator in June, almost three years after a comprehensive remediation process was initiated.

The nature of the inspection – whether it is a PAI (pre-approval inspection) or a GMP (good manufacturing practices) – could not be

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practices) – could not be ascertained.

ascertained. When contacted, Sun Pharma said it had no comment to offer.

The USFDA inspection at Halol in 2015 had resulted in 23 observations – a set of deficiencies in the manufacturing processes. The next inspection in 2016 resulted in nine observations and the last one conducted in February this year had cited three observations.

Interestingly, earlier this month Sun Pharma had announced a product recall of 5,215 units of 10 ml vials of testosterone cypionate injections from the US market. The product was manufactured at Halol. The reason for the recall cited in media reports was the presence of particulate matter – organic and inorganic compounds detected in vials of the product.

But it is unclear if the current inspection is actually triggered by the same recall or it is a smaller one only to approve a product or a few products. Pre-approval inspections are conducted if the USFDA intends to examine a site for approval of a single or a few products.

Read more on Sun Pharma | Halol Facility | USFDA | Sun Pharmaceuticals | Halol

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Lupin gets EIR from USFDA for Nagpur facility

PTI | Aug 24, 2018, 11.30 PM IST

A regulatory filing Lupin had said that the USFDA had completed inspection of the Nagpur facility without making any observations

Drug firm Lupin on Friday said it has received an establishment investigation report (EIR) from the US health regulator after the successful inspection of its Nagpur facility. The plant was inspected by the United States Food and Drug Administration (USFDA) in May 2018, Lupin said in a filing to BSE.

Commenting on the development, Lupin MD Nilesh Gupta said, "The successful completion of the Nagpur facility inspection is a positive development as we continue our journey to meet and exceed international regulatory standards."

Earlier in May, in a regulatory filing Lupin had said that the USFDA had completed inspection of the Nagpur facility without making any observations. Shares of Lupin were on Friday trading at 903 per scrip on BSE, down 0.07% from its previous close.

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US Medicare could have saved $1 billion by substituting branded drugs, says study

By *Rema Nagarajan*, TNN | Aug 24, 2018, 10.18 AM IST

The use of branded combination medicines instead of generic ones added almost a billion dollars in just one year to the cost of the US federal insurance programme.

The use of branded combination medicines instead of generic ones added almost a billion dollars in just one year to the cost of the US federal insurance programme, according to a study published in the Journal of the American Medical Association (JAMA). The study said promoting generic substitution by educating doctors on prescribing habits and through rational substitution policies could offer substantial savings to the drug benefit programme.

The revelation is significant for India since Indian pharma companies supply 40 per cent of generic drugs consumed in the US.

In 2016, the difference between what the Medicare drug benefit program spent on branded combination drugs and the estimated amount it would have spent for the same number of doses of generics was $925 million, concluded the study. The study conducted by doctors

at Brigham and Women's Hospital and Harvard Medical School analysed data from the prescription drug coverage programme in the 2011-16 period for 1,500 medications that accounted for the highest total spending reported by Medicare in 2015.

Medicare is a federal health insurance programme for those over 65 and for certain others such as younger people with disabilities and those with end-stage renal disease.

"For the 10 most costly brand-name combination drugs, the cumulative potential reduction in spending between 2011 and 2016 was estimated at $2.7 billion. Taking into account possible rebates from manufacturers at the average rate reported by Medicare, potential savings would have been estimated at $2.1 billion in total," stated the study.

The study cited the case of the antihypertensive drug Exforge, a combination of amlodipine and valsartan, that cost $8.21 per pill in 2016 compared to $0.96 for its generic constituents. It noted that with 5,036 beneficiaries prescribed Exforge in 2016, the estimated potential reduction in reported spending on just this one drug could have been $6.8 million. Similarly, the Medicare-reported price in 2016 for Duexis was $20.26 per pill compared to $0.28 for its generic constituents, ibuprofen and famotidine. For the 5,907 beneficiaries prescribed Duexis in 2016, the estimated saving could have been $23.4 million.

The researchers pointed out that while the prices of branded drugs have increased considerably in recent years, those of generic drugs has continued to decrease, which could explain the huge price difference and hence saving in cost.

The authors cited several studies to also point out that though combination products are said to reduce a patient's pill burden and improve adherence, no clear connection between combination products, improved adherence and improved clinical outcomes has been established.

The US has the highest per capita spending on prescription medications among industrialised countries and high drug costs have been a cause for concern for patients, doctors and policymakers.

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

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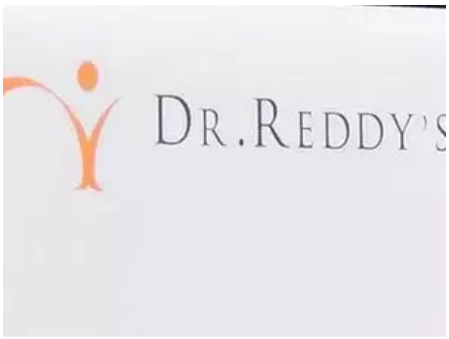
Dr Reddy's Labs gets EIR from USFDA for Srikakulam unit

PTI | Aug 23, 2018, 02.55 PM IST



In an earlier filing on June 2, 2018, the company had said that the audit of the Srikakulam plant (SEZ) by USFDA had been completed with no observations.

Dr Reddy's Laboratories today said it has received an Establishment Inspection Report (EIR) from the US health regulator for its Srikakulam facility in Andhra Pradesh.The Srikakulam unit manufactures active pharmaceutical ingredients (APIs).

The EIR from the United States Food and Drug Administration (USFDA) indicates closure of the audit of the plant, Dr Reddy's Labs said in a BSE filing.

In an earlier filing on June 2, 2018, the company had said that the audit of the Srikakulam plant (SEZ) by USFDA had been completed with no observations.

Shares of Dr Reddy's Labs were trading at Rs 2,467.05 per scrip on BSE, up 2.26 per cent from the previous close.

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Lupin enters prescription dermatology segment in Brazil

PTI | Aug 23, 2018, 01.59 PM IST

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Drug maker Lupin today said it has entered the prescription dermatology segment in Brazil with the launch of two products Fillerina and Recrexina in the country. Fillerina is a high-end anti-aging technology that

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Lupin today said it has entered the prescription dermatology segment in Brazil with the launch of two products Fillerina and Recrexina in the country.

incorporates a deep action innovative formulation to fill wrinkles and expression lines. Recrexina, on the other hand, is a hair-growth formulation which stimulates natural hair growth in active and partially inactive follicles.

"The launch of Lupin high-end skin science is a recognition of Lupin Brazil's capabilities within the pharmaceutical market, and with the launch of Fillerina and Recrexina, we look to executing on our capabilities in this sector and address the dermatological needs of the market," Lupin Latin America President Martin Mercer said in a statement.

The dermatology segment is a rapidly growing portion of the Brazilian pharmaceutical market, he added.

"The establishment of this new division to cater to Brazil's fast growing dermatological segment will further strengthen our presence in the region and serve to drive our future expansion plans," Mercer said.

Valued at USD 28 billion, Brazil is the world's sixth largest pharmaceutical market, driven by growing public health expenditure and increasing household income.

The dermatology segment in Brazil is worth USD 1.5 billion and growing at 10 per cent (CAGR) is one of the fastest growing segments in the country.

Lupin Brazil clocked sales of BRL 157 million during 2017-18 making it the largest Indian company in Brazil by volume and second largest by value.

The Mumbai-based company entered Brazil through the acquisition of Medquimica Industria Farmaceutica SA in 2015.

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Focus on 20 key brands to drive growth: GlaxoSmithKline pharmaceuticals

PTI | Aug 21, 2018, 04.56 PM IST

As part of its growth plans the company is also planning to aggressively expand its field force.

Drug firm GlaxoSmithKline Pharmaceuticals today said it has decided to concentrate on 20 key brands to drive growth going forward.

"In keeping with our global approach on focusing our energy where it matters, GSK India has decided to focus on 20 key brands to drive growth in identified therapy areas," GSK India spokesperson said in an e-mailed response.

As part of its growth plans the company is also planning to aggressively expand its field force.

"We will drive growth by increasing our field force by 30 per cent, from our current base," the spokesperson added.

Recently, while announcing the company's quarterly results, GlaxoSmithKline Pharmaceuticals MD A Vaidheesh had said: "... we are evolving our commercial operating model to invest resources on key products and patients/consumers to drive growth for our company".

Identified therapies will also be supported by incremental field force during the course of the year, he had said.

The company currently sells around 130 prescription drugs, vaccines and non prescription products in India.

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