Drug Information Bulletin

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Content

Editorial

India has developed a mechanism since 1979, when the price of about 350 drugs was under price control and it has been reduced to 74 in 1995, which is continuing till the last week. On 17th May 2013 Govt. has notified Drug (Price Control) Order 2013, which will control the price of all 348 Essential Medicines enlisted under National List of Essential Medicines (NLEM) 2011. The major change in the new DPCO is shifting the basis of price fixation from "manufacturing cost based" to "market based" mechanism. The prices of these 348 medicines are to be capped at the arithmetic average of all drugs in a particular therapeutic segment with more than one per cent market share. Most significant development in this order is that the price of "new drugs" will be fixed on the basis of "Pharmacoeconomic" principle, which is one of the modern concepts introduced formally in India first time. Complete text is available at http://pharmaceuticals.gov.in/rightpharma.htm. One sector believe that this market based mechanism will strike a balance between the affordability, but other sector are skeptical about its impact, who believe manufacturing cost based mechanism could have been more effective to improve affordability. Though immediate reaction from different quarter is mixed, its actual impact will be estimated after actual implementation of the order.

FDA approves Golimumab injection for ulcerative colitis

The Wall Street Journal reports that the Food and Drug Administration announced Wednesday that it has approved Simponi (golimumab), an injectable drug developed by Johnson & Johnson's Janssen Biotech division to treat adults with ulcerative colitis.

The AP adds that the FDA approved Simponi in 2009 to treat rheumatoid arthritis. Under the new indication, the agency approved Simponi to treat adults whose ulcerative colitis is not relived by "conventional therapy" and for those who

must rely on "continuous steroid use." The chronic condition affects "about 620,000 people in the US," the FDA noted in the announcement.
Bloomberg News notes that Simponi "generated $607 million in sales last year, a figure that may double to $1.2 billion by 2016, according to the average of four analysts' estimates." However, the treatment is not without competition. The FDA approved Abbott Laboratories' "best-selling arthritis treatment Humira [adalimumab] on Sept. 28 for ulcerative colitis." In addition, J&J's own "$6 billion drug Remicade [infliximab]" has approval as an ulcerative colitis therapy; and Pfizer is testing its own RA treatment, Xeljanz (tofacitinib citrate), for use by patients with the chronic bowel disease.

Generic drug maker pleads guilty in federal case

The generic drug maker Ranbaxy pleaded guilty on Monday to federal drug safety violations and will pay $500 million in fines to resolve claims that it sold subpar drugs and made false statements to the Food and Drug Administration about its manufacturing practices at two factories in India, the company and federal prosecutors announced Monday. The settlement is the largest in history involving a generic manufacturer and drug safety, the Justice Department said.

Ranbaxy has been operating under a consent decree with the Food and Drug Administration since last year after federal officials identified a host of manufacturing lapses at plants in India and one in the United States, and concluded that the company, which is a subsidiary of the Japanese pharmaceutical company Daiichi Sankyo, submitted false data to the F.D.A. Ranbaxy has not exported drugs from the two Indian factories, known as Paonta Sahib and Dewas, to the United States since 2008.

As part of the settlement on Monday, Ranbaxy pleaded guilty to three felony counts of violating the federal drug safety law and four of making false statements to the F.D.A. The company acknowledged that it failed to conduct proper safety and quality tests of several drugs manufactured at the Indian plants, including generic versions of many common medicines, like gabapentin, which treats epilepsy and nerve pain, and the antibiotic ciprofloxacin.

In the case of gabapentin — of special note because of the high stakes involved in treating patients with epilepsy — the company admitted that between June and August in 2007, it knew that certain batches had tested positive for “unknown impurities” and had unreliable shelf lives. But Ranbaxy waited until October of that year to alert the F.D.A. and announce a recall, which ultimately involved more than 73 million pills.

Ranbaxy workers were also lax in ensuring that certain batches of drugs remained effective throughout their estimated shelf life, and prosecutors said the company tested some products weeks or months after it told the F.D.A. that it had done so.

A Ranbaxy spokesman said the issues with gabapentin, also known as Neurontin, outlined in the plea agreement had no bearing on the safety or effectiveness of the drugs, and the F.D.A. said it did not receive any reports of patients being harmed by the drugs made at the plants in question.

In a statement Monday, Ranbaxy noted that the settlement involved conduct that occurred several years ago and said it had already set aside $500 million in anticipation of the penalties. The company is paying $150 million in a criminal fine and forfeiture, with the remainder going to settle civil claims brought by the federal government and all 50 states. A former Ranbaxy executive who alerted the federal government to the problems will receive close to $49 million in compensation for his role as a whistle-blower.

“Today’s announcement marks the resolution of this past issue,” Arun Sawhney, the chief executive of Ranbaxy, said in the statement. “We are pleased to continue bringing safe, effective and quality medicines to market for the benefit of consumers in the U.S. and other parts of the world.”

Ranbaxy’s troubles have not been limited to the lapses outlined in the federal settlement. Last November, the company halted production of generic Lipitor while it investigated why glass particles turned up in pills distributed to the public. The problem was traced to a cracked glass lining in a tank at another plant in India and Ranbaxy resumed production in February.

“I think what comes out of this suit is that Ranbaxy has really deep problems with quality control, and this case was essentially the canary in the coal mine,” said Patrick Burns, a spokesman for Taxpayers Against Fraud, a whistle-blower advocacy group.

Others say the company’s problems highlight how little oversight federal drug safety officials have of overseas plants. Studies that have shown the F.D.A. inspects foreign generic manufacturing plants about once every seven to 13 years, compared with once every two years for domestic manufacturers. A law passed last year will eventually require the F.D.A. to apply the same standards when inspecting all manufacturing plants, regardless of location. But some worry that federal budget cuts are slowing the adoption of that law.

“They just happened to stumble across the Ranbaxy problem at those two plants in India,” said Joe Graedon, a pharmacologist who runs a consumer Web site, the People’s Pharmacy, which has raised questions about the safety of generic drugs. “Ranbaxy was the biggest and one of the best in India. What about all the smaller ones? What does that say about them?”

Those who defend the generic-drug industry point out that the overwhelming majority of generic products are as safe and effective as their brand-name counterparts. And brand-name companies have encountered their share of quality problems: Johnson & Johnson is operating under a consent decree because of problems at manufacturing plants, and in 2010, the drug maker GlaxoSmithKline paid $750 million in criminal and civil fines to resolve a federal whistle-blower suit that highlighted problems at a factory in Puerto Rico.

Mr. Burns said the recent cases — and the large rewards earned by whistle-blowers — show that there is a renewed focus on drug quality. “The point is, the government is willing to pay money in order to catch these people and that’s a very strong message,” he said. “Hopefully it’s also a strong message for companies that they have got to clean up their act.”

Sanofi fined $52.8 Million for denigrating Plavix copies

Sanofi (SAN), France's largest drugmaker, was fined 40.6 million euros ($52.8 million) by the country's competition regulator for trying to limit sales of generic versions of the company's Plavix blood thinner.

Sanofi denigrated the copies of the drug to doctors and pharmacists, the regulator said in a statement on its website today. The Competition Authority was acting on a complaint by Teva Pharmaceutical Industries Ltd. (TEVA), the world's biggest maker of generic medicines.

Plavix had sales of 2.07 billion euros last year. In 2008, France's national health system paid 625 million euros on the drug, the most of any pharmaceutical, the competition regulator said.

Sanofi's sales force cast doubt on the efficacy of competing generics in conversations with doctors and pharmacists in 2009 and 2010, and warned that they could be liable if patients had medical problems after using the copies, according to the statement.

Sanofi urged doctors to write on prescriptions that the generic version couldn't be substituted for the branded product, the competition regulator said. The Paris-based company also urged pharmacists, when using a generic, to use Sanofi's own generic rather than one from a competitor, according to the statement.

"Sanofi disagrees with the Competition Authority's decision, and is currently reviewing all the points to prepare an appeal before the Paris appeals court," the company said in an e-mailed statement. "The safety of patients is Sanofi's first priority."

Source: Bloomberg.com

Directorate of pharmacy need to be established in each state to check drug related matters

To address the issues related to drugs and other pharmaceutical products and also to ensure the quality of medicines manufactured and supplied, separate directorate of pharmacy (ED) should be established in each state under health departments.

Unless there is a proper set up with trained man power administration all the attempts to check the drug related issues will remain futile and the dangers posed by spurious drugs on public health will become uncontrollable, said Dr R S Thakur, president, federation of Indian pharmacists organisations (FIPO), New Delhi.

In a chat with Pharmabiz, he said lack of due importance to pharmacy services in healthcare management is the root cause of all the menace affecting the quality of drugs. FIPO has made a demand before the government of India to initiate steps to establish separate directorate for pharmacy in all the states through separate legislation.

"The first and foremost issue in relation to procurement and handling of drugs is that it cannot be treated as any other item of commerce or commodity of day to day use. Drugs are two edged weapon, which can both cure or kill. Right use of right drug in right dose at right time through right route of administration can save precious life, whereas, a substandard drug product, be it misbranded, adulterated or spurious, may not only fail in giving any relief to the patient but also toxic and lead to new complications. As long as this vital difference between drug and other commodities is not fully appreciated and pharmacists are not solely involved in all aspects relating to them, the menace of spurious and substandard drugs will continue to exist," Dr Thakur commented.