Drug Information Bulletin

Drug Information Centre (DIC)
Indian Pharmaceutical Association
Bengal Branch
Tele fax: 033 24612776, E-mail: ipabengal.dic@gmail.com
Web Site: http://www.ipabengal.org
Contact: 09830136291

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Content

- **Editorial**
- **Generic drug companies reach $2.15B settlement with Pfizer in patent infringement case**
- **Dextropropoxyphene and its formulation banned in India with effect from 23.05.2013**
- **French 'sunshine act' sheds little light on drug industry's payments to doctors, say critics**
- Executive Director of PMNC said that Nutrition is the spotlight this month

Editorial

The World Health Organization (WHO) has issued interim guidance on the use of Bedaquiline on 13th June 2013, the first new drug to treat tuberculosis in more than 40 years after Rifampicin, acknowledging the growing crisis of multidrug-resistant TB (MDR-TB) and the urgent need for improved drugs with better efficacy and safety profiles. This step of WHO to make interim recommendations about a drug based on phase IIb clinical trial data is considered as an unprecedented. Bedaquiline received accelerated approval by the US Food and Drug Administration (USFDA) on 31 December 2012. Bedaquiline affects the proton pump for ATP synthase. In India clinical trial is going on this drug. The entire development encouraging the treatment of DR-TB patients.

Generic drug companies reach $2.15B settlement with Pfizer in patent infringement case

The Wall Street Journal reports Israel-based Teva Pharmaceutical Industries Ltd. and India-based Sun Pharmaceuticals Ltd. Will pay a combined $2.15 billion in patent infringement damages to Pfizer Inc. and Takeda Pharmaceutical Co. for selling generic copies of heartburn medication Protonix (pantoprazole) before the drug's patent expired in the US. New York-based Pfizer will see 64% of the total, and Japan's Takeda will take the rest. The settlement is the result of an "at-risk" launch of a generic drug, a technique used by aggressive generic medication manufacturers to get their versions of brand-name drugs to market before patent litigation has ended. After challenging a validity of a patent for a popular drug, generic companies immediately sell their copies upon receiving approval from the FDA and a 30-month delay due to the filing of a patent-infringement lawsuit by the patent holder.

Teva will pay $1.6 billion in the settlement, with $800 split over the next two years. Sun will pay the remaining $550 million. The companies started to sell generic versions of Protonix "in 2008 only to lose a challenge to a patent on the medicine two years later.

Dextropropoxyphene and its formulation banned in India with effect from 23.05.2013

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स्वास्थ्य और परिवार कल्याण मंत्रालय

(स्वास्थ्य और परिवार कल्याण विभाग)

अधिसूचना

नई दिल्ली, 23 मई, 2013

सा.का.नि. 332(अ).—जबकि केंद्र सरकार संतुष्ट है कि डेक्सट्रायरोप्रोपाक्सीफीन औषध और ऐसे फार्मूलेशन जिसमें डेक्सट्रोप्रोपाक्सीफीन शामिल हो, के प्रयोग से मानव जीवन को जोखिम की संभावना है और जबकि उक्त औषध के सुरक्षित विकल्प उपलब्ध हैं;

और जबकि केंद्र सरकार संतुष्ट है कि जनहित में देश में औषधों का विनिर्माण, बिक्री तथा वितरण के निलंबन द्वारा नियंत्रित करने तथा ऐसी शीघ्र कार्रवाई करने की जरूरत है;

अतः अब, औषध एवं प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 26क द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, केन्द्र सरकार एतद्द्वारा तत्काल प्रभाव से निम्नलिखित औषधों की बिक्री के लिए विनिर्माण, बिक्री और वितरण को निलंबित करती है।

'डेक्सट्रायरोप्रोपाक्सीफीन' और मानव उपयोग के लिए ऐसे फार्मूलेशन जिसमें डेक्सट्रोप्रोपाक्सीफीन शामिल हो।

[फा. सं. एक्स. 11014/1/2013-डीएफक्यूसी]

अरुण कुमार पण्डा, संयुक्त सचिव

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 23rd May, 2013

G.S.R. 332(E).—Whereas the Central Government is satisfied that the use of the drug Dextyropropoxyphene and formulations containing Dextropropoxyphene for human use is likely to involve risk to human beings and whereas safer alternatives to the said drugs are available;

And whereas the Central Government is satisfied that it is necessary and expedient to regulate by way of suspension of manufacture, sale and distribution of the drugs in the country in public interest;

Now therefore, in exercise of the powers conferred by section 26A of the Drugs and Cosmetic Act, 1940 (23 of 1940), the Central Government hereby suspend the manufacture for sale, sale and distribution of the following drugs with immediate effect.

'Dextyropropoxyphene and formulations containing Dextropropoxyphene for human use'.

[F. No. X. 11014/1/2013-DFQC]

ARUN K. PANDA, Jt. Secy.

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French 'sunshine act' sheds little light on drug industry's payments to doctors, say critics

The French government passed into law its long awaited version of a 'sunshine act' on 22 May, putting a legal obligation on drug companies to reveal the financial gifts they bestow on healthcare practitioners.

Marisol Touraine, the minister of social affairs and health, said that the act was intended to provide a moral underpinning on 'the relations between industry and the world of health.'

The new bill, which aims to prevent conflicts of interests, is a reference to the US Sunshine Act (Physician Financial Transparency Reports), which was included in the Affordable Care Act 2010. In the United States drug and medical device companies are expected to start disclosing almost all financial relations with doctors including payments for research, consulting, speaking engagements, and even meals later this year. 1

However, despite a nine month consultation on the French act, critics have said that the new regulations have been so watered down that they stop far short of full transparency. They have complained that the act serves the interests of the drug industry more than those of patients.2

The new law applies to manufacturers of cosmetics as well as drug and device companies. Information on financial benefits over a threshold value of 10 Euros (8.5; $13) will be posted on a website in the future under the responsibility of an authority that is yet to be determined. In the meantime the identity of the recipient, the amount of money paid, and nature of the benefit will be posted on the company's website and on the website of the professional organisation to which the recipient belongs.However, the new act requires companies to disclose only payments to healthcare professionals that are regarded as gifts, including meals and entertainment. It does not include payments done for work undertaken.French law already requires that national councils of healthcare professionals must be told of all work contracts between a company and a healthcare professional, although the amount of the money they are being paid does not need to be disclosed.
Critics have highlighted the fact that under the new law the amount of money spent on a meal paid for by a company would be made public but that a large sum of money paid in return for a tiny piece of work would remain hidden.

The French National Medical Council has said that the rules are not fit for purpose. A spokesperson said, "We have decided to lodge an appeal, and our legal experts are considering the best form to make it change."

The Medicines in Europe Forum, which aims to ensure that European pharmaceutical policy serves patients' interests, described the law as having "unacceptable opacity."

References

1. Epstein K. US to require public disclosure of drug and device industry's financial ties to doctors. BMJ2012;344:e515.

2. Benkimoun P. Plan to force drug companies in France to reveal payments to doctors has been diluted, campaigners say. BMJ2012; 345:e8405.

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Executive Director of PMNC said that Nutrition is the spotlight this month

Nutrition is the spotlight this month, as we approach the G8 Summit in Fermanagh, Northern Ireland and embark on the3 phase toward a post-2015 development framework to replace the UNs MDGs.

At a high-level summit in London on 8 June, hosted by the governments of the United Kingdom and Brazil with the Children's Investment Fund Foundation, representatives from developing and developed nations, businesses, and scientific and civil society groups agreed to a historic reduction in undernutrition. The Partnership for Maternal, Newborn & Child Health welcomes their signing a Global Nutrition for Growth Compact, backed up by commitments of up to $4.15 billion. Many PMNCH partners contributed to this excellent result, including pledges from the Bill & Melinda Gates Foundation, Save the Children, the World Bank Group, World Vision, and the governments of Canada and the United Kingdom promising millions in new funding.

Tackling malnutrition is crucial to accelerating progress in women's and children's health. Undernutrition can lead to health problems across generations, particularly among the most vulnerable populations. Meanwhile the number of overweight and obese women and children is increasing among low and middle-income countries, contributing to a higher prevalence of chronic noncommunicable diseases and associated healthcare costs.

PMNCH has been underlining the link between nutrition and sustainable development with a two-page evidence summary on investing in nutrition, developed for the Open Working Group of the UN General Assembly, which is tasked with preparing a proposal on sustainable development goals as part of the UN post-2015 development agenda process.

Knowledge Summary #18: Nutrition, produced by PMNCH and partners in 2012, has also been a valuable tool for raising awareness about the so-called double burden of malnutrition. And now new light has been shed on this issue with the latest nutrition series published in *The Lancet*, which also assesses national progress in nutrition programmes and international efforts toward previous recommendations.

Transparency and accountability being the stated focus of this year's G8 Summit, leaders should be especially motivated to see pledges result in measurable action. Bringing commitments to invest in nutrition under the umbrella of the Every Woman Every Child movement led by UN Secretary-General Ban Ki-moon would provide a useful framework for tracking their progress. We look forward to supporting efforts in this direction.