Drug Information Bulletin

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Content

Editorial

Agreement of Aurobindo Pharma with Medicines Patent Pool(NPP) for supplying Abacavir to 118 countries for the treatment of paediatric HIV is encouraging news for the patients living with HIV and the health care managers of most of the countries. As per the World Health Organization (WHO) estimate there are currently 3.4 million children living with HIV worldwide but only 562,000 of them have access to medicines. Already a number of Institutions and companies have joined MPP. Hope more new organizations will join it in near future.

Government to bring bill to regulate medical equipment sector

The Government will soon bring a Bill which is aimed at regulating the medical equipments industry in the country which so far has remained unregulated.

The new Bill will replace the existing Drugs and Cosmetics (Amendment) Bill, 2007 which is pending in Parliament and will have to be withdrawn.

Giving this information here today, Joint Secretary in the Health Ministry Arun Kumar Panda said regulation of medical devices industry has been a major challenge for the government and present thousands of such equipments are used in an unregulated manner.

The government will soon put up before the Cabinet the new bill which will have a separate chapter on medical devices, he said addressing a seminar -- 'Harnessing Medical Technology for inclusive healthcare in India'.

The Bill provides for monitoring and setting standards for medical devices. The Bill, if passed, will help strengthen the domestic manufacturing industry and could make medical devices more

accessible and affordable to the people at large in the country.
Panda said India's pharmaceutical sector has made rapid strides in the last few years and "we still need to create a place of our own in the medical devices sector". He said the Government is keen on strengthening its regulatory body- Central Drugs Standard Control Organisation -- by providing more skilled manpower and better infrastructure in its offices across the country.
For that, the government has already allocated Rs 1800 crore at national level during the current 12th five year plan and Rs 1200 crores to the states for the same.

Aurobindo Pharma signs Medicines Patent Pool licence to make medicines for children living with HIV

Aurobindo Pharma Limited, a key producer of generic medicines, has signed an agreement with the Medicines Patent Pool that will allow it to produce key medicines for the treatment of children living with HIV.

Through a patent licence with the MPP, Aurobindo can now supply medicines containing abacavir in the 118 countries where 98.7% of children living with HIV reside. Abacavir is recommended by the World Health Organization for the treatment of paediatric HIV.

There are currently 3.4 million children living with HIV worldwide. But only 562,000 of them have access to medicines, according to the World Health Organization (WHO).

“Treating children living with HIV can be challenging, as medicines suited to their specific needs are often unavailable. With this licence, Aurobindo looks forward to increasing the supply of quality, child-friendly HIV treatment in developing countries,” said P.V. Ramaprasad Reddy, chairman of Aurobindo.

The Medicines Patent Pool made the abacavir licence available for generic companies following an agreement it signed with ViiV Healthcare [a joint venture of GlaxoSmithKline, Pfizer, and Shionogi] in February 2013.

“Quality medicines at affordable prices are critical for combatting the HIV epidemic, and generic manufacturers like Aurobindo are an essential part of ensuring such medicines are available,” said Greg Perry, Executive Director of the Medicines Patent Pool. “The agreement with ViiV is an important initial step towards making more child-friendly HIV medicines available where they are most needed.”

Aurobindo was also one of the first generic companies to take licences on several HIV medicines for adult use licensed to the Medicines Patent Pool by Gilead Sciences in July 2011.

FDA approves emergency contraceptive for use without a prescription for all women of child-bearing potential

Today, the U.S. Food and Drug Administration announced it has approved the use of Plan B One-Step (levonorgestrel) as a nonprescription product for all women of child-bearing potential. This action complies with the April 5, 2013 order of the United States District Court in New York to make levonorgestrel-containing emergency contraceptives available as an over-the-counter (OTC) product without age or point-of-sale restrictions.

Plan B One-Step is an emergency contraceptive intended to reduce the chance of pregnancy following unprotected sexual intercourse or a known or suspected contraceptive failure (e.g., condom). Plan B One-Step is a single-dose pill (1.5 mg tablet) that is effective in decreasing the chance of pregnancy and should be taken as soon as possible within three days after unprotected sex.

On June 10, 2013, the agency notified a United States District Court judge in New York of its intent to comply with the court's April 5, 2013 order instructing the FDA to make levonorgestrel-containing emergency contraceptives available as an over-the-counter (OTC) product without age or point-of-sale restrictions. To comply, the FDA asked Teva Women's Health, the manufacturer of Plan B One-Step, to submit a supplemental application seeking approval of the one-pill product to be made available without any restrictions. The agency has fulfilled its commitment to the court by promptly completing its review and approval of the supplemental application.

"Over-the-counter access to emergency contraceptive products has the potential to further decrease the rate of unintended pregnancies in the United States," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research.

Plan B One-Step was first approved in July 2009 for use without a prescription for women age 17 and older and as a prescription-only option for women younger than age 17. In April 2013, the product was approved for nonprescription use for women as young as 15. With this approval, the product is now available without a prescription for use by all women of reproductive potential.

The product contains higher levels of a hormone found in some types of daily use oral hormonal contraceptive pills and works in a similar way to these contraceptive pills by stopping ovulation and therefore preventing pregnancy.

Plan B One-Step will not stop a pregnancy when a woman is already pregnant and there is no medical evidence that the product will harm a developing fetus.

The product will not protect a woman from HIV/AIDS or other sexually transmitted diseases. It is important that young women who are sexually active see a health care provider for routine checkups. The health care provider should counsel the patient about, and test them for sexually transmitted diseases, discuss effective methods of routine birth control, and answer any other questions the patient may have.

Some women taking Plan B One-Step have reported experiencing the following side effects: nausea, vomiting, stomach pain, headache, dizziness and breast tenderness. These are similar to the side effects of regular prescription-only birth control pills.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

For details:
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm358082.htm

The National Pharmaceutical Pricing Authority has fixed / revised the prices in respect of more than 150 formulation packs by notification / orders

The National Pharmaceutical Pricing Authority (NPPA) has fixed / revised the prices in respect of more than 150 formulation packs by notification / orders as per the DPCO-2013, which are available at http://www.nppaindia.nic.in

FDA investigates multistate outbreak of Hepatitis a illnesses potentially associated with a frozen fruit blend

On June 14, The Jackson County Oregon Health Department warned customers of Evo's Coffee Lounge, in Ashland, Oregon, that they may have been exposed to Hepatitis A in the coffee shop's "Radically Free" smoothie served between May 17 and June 12, 2013. The coffee shop used Townsend Farms Organic Antioxidant Blend to produce this menu item. The Jackson County Health Department also alerted those who may have been exposed in the last 14 days of the availability of Hepatitis A vaccine in the local area.

Hepatitis A is a contagious liver disease that results from infection with the Hepatitis A virus. It can range in severity from a mild illness lasting a few weeks to a severe illness lasting several months. Hepatitis A is usually spread when a person ingests fecal matter — even in microscopic amounts — from contact with objects, food, or drinks contaminated by the feces, or stool, of an infected person.

Illness occurs within 15 to 50 days of exposure and includes fatigue, abdominal pain, jaundice, abnormal liver tests, dark urine and pale stool."

Kerala Drugs Control dept begins action against AKCDA to break its monopoly over drug distribution as per CCI order

Taking the order of the Competition Commission of India (CCI) against All India Organization of Chemists & Druggists (AIOCD) in February this year as a tool for resisting the opposition of trade associations, the drugs control department of Kerala has started stringent actions to break the monopoly of AKCDA, the affiliate of the national trade body in Kerala.

In February this year the CCI had issued a direction to the national trade body against its alleged unfair trade practices. CCI wanted the organization to stop and desist from indulging in practices that are anti-competitive in violation of Section 3 of the Competition Act. Besides, the Commission imposed a penalty of Rs.47,40,613 on the trade body for engaging in unfair trade practices.

For Details: Pharmabiz.com

Forthcoming Event:

Annual General Meeting
of IPA Bengal Branch
Date: 7th July 2013
Time: 5.00 pm
Venue:
IPA Auditorium
22 B Panchanontola Road
Kolkata-700029