Drug Information Bulletin

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Content

Editorial

Pharmaceutical Industries in India is gearing up for implementation of Schedule H1 from 1st March 2014 – about one and half months away from now. This editorial will remind them about the special requirements of Sch. H1.

It may be noted that Schedule H1 has been introduced in the Drugs & Cosmetics Rules vide a notification dated 30th August 2013, which is effective from 1st March 2014, and includes 46 drugs including antibiotics, drugs having potential for misuse etc. Out of 46 drugs, 26 drugs were shifted from Schedule H and 20 more drugs have been included in this schedule.

The main aim was to reduce irrational use of antibiotics, which is a major cause of developing resistance to antibiotics. It was noted that all medicines including antibiotics are available from community pharmacy over the counter in India. Thereafter some more medicines were included in this list as their irrational use created health hazards and social problems.

The sale of these drugs has made regulated imposing additional conditions. Firstly the label of the drugs should bear a warning-

"SCHEDULE H1 DRUG-WARNING
-it is dangerous to take this preparation except in accordance with the medical advice.
-not to be sold without the prescription of a registered medical practitioner"

Label should contain RX symbol in red color at the left top corner. Supply of a drug included in Sch. H1 requires to be recorded in a separate register at the time of supply including the Name & address of the prescriber, Name & address of the patient, Name of the drug and quantity supplied. The record requires to be preserved for 3 years and made ready for inspection.

Experts feel that the restrictions prescribed for dispensing of Schedule H drugs are not being implemented properly, leading to irrational and misuse of medicines. They expect stricter enforcement of the restrictions imposed in case of dispensing of Schedule H1 medicines by the regulatory mechanism for the sake of public health.

NPPA asks manufacturers to suo-moto pay dues on drugs sold at higher prices still after 15 days of price revision

The National Pharmaceutical Pricing Authority (NPPA) has asked the drug manufacturers to suo-moto work out the overcharged amount by themselves in respect of drugs sold without implementing the new price revision and deposit the money with the government along with interest.
The NPPA, through letters sent to all the leading industry bodies, made this direction following the Supreme Court dismissal of the petitions filed by some manufacturers regarding the provisions of the DPCO to implement the price revision within 15 days from the date of notification.

"As part of self-regulatory exercise, you are requested to advise your member units to suo-moto work out the overcharged amount by themselves in respect of quantities manufactured before issue of the price notification order but sod to the consumer/public at higher price without implementing the new revised price even after expiry of the 15 days as specified in paragraph 14(1) of DPCO, 1995 duly certified by chartered /cost accountant and deposit the same with the government along interest at the rate of 15 per cent per annum due thereon," said a notice by the NPPA.

As per the Paragraph 14(1) of the DPCO, 1995, every manufacturer or importer is required to carry into the effect of price of a bulk drug or formulation as the case may be fixed by the government from time to time, within 15 days from the date of notification in the official gazette or receipt of the order of the government in this behalf by such manufacturer or importer.

The Supreme Court however dismissed the appeals by the manufacturers in this regard and upheld the stand of the NPPA through a judgment on December 9, 2013 and clarified the position.

"The judgment has upheld NPPA's stand that the companies would be required to implement the notified revised price in respect of the old bathes which were manufactured before the issue of the said notification but sold to the consumer after expiry of 15 days from the date of issue of notification," the NPPA notice said.

"It may be apprehended that there may be the large number of cases where the companies may not have implemented the revised price in respect of the quantity manufactured prior to the issue of the price notification order and continued to sell at pre-revised price even after expiry of 15 days from the date of notification," the NPPA said while asking the companies to follow the rule and pay the dues suo-moto.

Penalties are coming for drug makers in India that have overcharged

Drug makers are facing penalties now that the National Pharmaceutical Pricing Authority in India has started calculating the amount they overcharged when they sold old stocks of price-controlled medicines at unrevised prices over the past 10 years. When the NPPA changes drug prices, many companies sell off existing stock at the former prices and new stocks at the revised prices, a practice that the country's Supreme Court ruled against in a case involving GlaxoSmithKline last month. Some in the pharma community say the information will be difficult to obtain, but this course

could be damaging to the pharmaceutical industry if the NPPA pursues it.
Source: The Economic Times (India)

Physicians protest German proposal to drop drug-assessment program

German doctors are fighting proposals by the new coalition government to drop a 2010 program that requires a cost-benefit analysis of new drugs demonstrating that they provide better patient treatment than existing medications before companies can charge a higher price. The analyses are conducted by a committee composed of physicians, hospitals and insurance firms. "The benefit analysts for those medications already on the market is essential for a high-quality and economic medicines provision," said Wolf-Dieter Ludwig, chairman of the German Medical Association. PharmaTimes (U.K.)

11 drug compounders registered with FDA through Thursday

Eleven drug compounders have registered with the FDA hoping that this would give them a marketing advantage under the Drug Quality and Security Act. The facilities, posted Thursday on the agency's website, join a new class of compounders called outsourcing facilities that will have to pay a fee, face routine inspections, report adverse events tied to their products and follow good manufacturing standards. "We're hopeful that market forces will drive more firms to register with FDA as outsourcers, but only time will tell," said FDA spokesman Steven Immergut.
Source: Reuters

Bone marrow stem cells could defeat drug-resistant tuberculosis

Patients with potentially fatal "superbug" forms of tuberculosis (TB) could in future be treated using stem cells taken from their own bone marrow, according to the results of an early-stage trial of the technique.

The finding, made by British and Swedish scientists, could pave the way for the development of a new treatment for the estimated 450,000 people worldwide who have multi drug-resistant (MDR) or extensively drug-resistant (XDR) TB.

In a study in The Lancet Respiratory Medicine journal on Thursday, researchers said more than half of 30 drug-resistant TB patients treated with a transfusion of their own bone marrow stem cells were cured of the disease after six months.

"The results ... show that the current challenges and difficulties of treating MDR-TB are not insurmountable, and they bring a unique opportunity with a fresh solution to treat hundreds of thousands of people who die unnecessarily," said TB expert Alimuddin Zumla at University College London, who co-led the study.

TB, which infects the lungs and can spread from one person to another through coughing and sneezing, is often falsely thought of as a disease of the past.

In recent years, drug-resistant strains of the disease have spread around the world, batting off standard antibiotic drug treatments.

The World Health Organization (WHO) estimates that in Eastern Europe, Asia and South Africa 450,000 people have MDR-TB, and around half of these will fail to respond to existing treatments.

TB bacteria trigger an inflammatory response in immune cells and surrounding lung tissue that can cause immune dysfunction and tissue damage.

Bone-marrow stem cells are known to migrate to areas of lung injury and inflammation and repair damaged tissue. Since they also modify the body's immune response and could boost the clearance of TB bacteria, Zumla and his colleague, Markus Maeurer from Stockholm's Karolinska University

Hospital, wanted to test them in patients with the disease.

In a phase 1 trial, 30 patients with either MDR or XDR TB aged between 21 and 65 who were receiving standard TB antibiotic treatment were also given an infusion of around 10 million of their own stem cells.

The cells were obtained from the patient's own bone marrow, then grown into large numbers in the laboratory before being re-transfused into the same patient, the researchers explained.

During six months of follow-up, the researchers found that the infusion treatment was generally safe and well tolerated, with no serious side effects recorded. The most common non-serious side effects were high cholesterol levels, nausea, low white blood cell counts and diarrhea.

Although a phase 1 trial is primarily designed only to test a treatment's safety, the scientists said further analyses of the results showed that 16 patients treated with stem cells were deemed cured at 18 months compared with only five of 30 TB patients not treated with stem cells.

Maeurer stressed that further trials with more patients and longer follow-up were needed to better establish how safe and effective the stem cell treatment was.

But if future tests were successful, he said, it could become a viable extra new treatment for patients with MDR-TB who do not respond to conventional drug treatment or those with severe lung damage.

Source: Reuters

Scientists develop personalized prostate cancer treatments

Advances in genomics are allowing researchers to identify prostate and other cancer tumors that are likely to respond to less-aggressive treatment as well as those that may need highly aggressive treatment. Researchers are testing combination approaches in prostate cancer that are similar to those used to treat some breast cancers, based on the tumors' genetic profiles.

Source: The Wall Street Journal

Presence of heavy metals in cosmetics

One of India's largest studies on the presence of heavy metals in cosmetics has emerged with a startling finding: the fairness creams – ones which are endorsed by some of our biggest Bollywood names – could contain mercury, an element which is universally recognised as extremely toxic. Lipsticks, which many of us can't do without, may come packed with chromium, which is carcinogenic.Centre for Science and Environment's (CSE's) Pollution Monitoring Lab (PML), which did the study, says use of mercury in cosmetics is prohibited in India. PML found mercury in 44 per cent of the fairness creams it tested. It also found chromium in 50 per cent and nickel in 43 per cent of the lipstick samples it tested. The lab also tested for lead and cadmium, but did not find any.

For details: http://www.cseindia.org/node/5293

Pic from recently concluded Health Camp at Gangasagar organized by IPA, Bengal Branch & IPA Bengal Pharma & Health Care Trust