Drug Information Bulletin

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Content

Editorial

Indian market is flooded with FDCs. Several sources quoted different numbers ranging from 60,000 – 100000. Though there is handful of FDCs having advantage over single ingredient products, there is hardly any benefit of most of the FDCs. As per the experts this situation becomes more complicated due to unregulated approval of FDCs by some state licensing authorities. Sometimes back DCGI published a list of FDCs as irrational, but those are still available in the market as a result of a stay order by Madras High Court. Again DCGI has given a direction to submit Safety and Efficacy data of the FDCs available in the market without approval from the DCGI with a deadline on 30th August 2013. Everybody is waiting eagerly to see the fate of this direction.

Suspension of three medicines to get review in India

India's Drug Technical Advisory Board (DTAB) is likely to review on July 19 the suspension of the production and sale of the antidepressant Deanxit, the pain drug Analgin and the diabetes treatment Pioglitazone. Drug industry representatives are expected to join the meeting to present clinical and scientific information. "The drugs are merely suspended and not banned," a senior official said. "However, since these are widely prescribed medicines and some experts have said a permanent ban may have price impacts on patients, we have

asked the industry to submit data to support their case."

Schedule H1 antibiotics to be limited to only 48 instead of 91 proposed earlier

The Government will include only 48 antibiotics in the proposed Schedule H1, instead of 91 antibiotics as planned in the original proposal. The notification to include this as a separate new Schedule aimed at monitoring and regulating the sale of antibiotics in the country is expected soon.

According to the new proposal, cleared by the Drugs Technical Advisory Board (DTAB), the Schedule H1 will have only third, fourth generation and carbapenum class of antibiotics. Besides, it will also include some anti-TB and habit forming drugs, without affecting the national TB control programme.

Another change in rules will be omission of having two prescriptions to buy these antibiotics. The DTAB has recommended that “in order to keep a check or monitor the sale of such drugs, a condition should be incorporated under Rule 65 that the supply of any drug covered in the Schedule shall be recorded in a separate register at the time of supply giving the name and address of the prescriber, the name of the patient and name of the drug and the quantity supplied. These records shall be maintained for three years and open for inspection.”

As many as 24 antibiotics falling under third and fourth generationn antibiotics and Carbapenum groups of drugs will be among the drugs to be plaed in the Schedule H1. They are Meropenem, Imipenem, Ertapenem, Doripenem, Feropenem, Balofloxacin, Cefdinir, Cefditoren, Cefepime, Cefetamet, Cefixime, Cefoperazone, Cefotaxime, Cefpirome, Cefpodoxime, Ceftazidime, Ceftibuten, Ceftizoxime, Ceftriaxone, Gemifloxacin, Levofloxacin, Moxifloxacin, Prulifloxacin and Sparfloxacin.

The habit forming drugs to be included in the Schedule are Alprazolam, Buprenorphine, Chlordiazepoxide, Codeine, Dextroropoxyphene, Diazepam, Diphenoxylate, Midazolam, Nitrazepam, Pentazocine, Propoxyphene, Tramadol and Zolpidem.

There are going to be 11 anti-TB drugs. They are Ethambutol Hydrochloride, Isoniazid, Pyrazinamide, Rifampicin, Ethionamide, Cycloserine. Sodium Para-aminosalicylate, Rifabutin, Capreomycin, Clofazimine, and Thiacetazone.

The Government had already published draft rule in March 2012 for incorporating the separate Schedule H1. The notification had included 91 antibiotics and the provision for double prescription for the purpose of auditing so as to find out how these drugs are being sold and used. It was based on the recommendation by a Task Force set up by the Government to assess, review and suggest measures to contain anti-microbial resistance.

However, the proposal ran into rough weather with trade bodies and practitioners raising apprehensions and protests over the practical difficulties and possible decline in sales. The Government hence had decided to review the proposal and sent to the DTAB.

AHRQ Primer discusses using checklists to reduce the risk of health care errors

Most errors in healthcare are defined as slips rather than mistakes, and checklists

can help prevent them, according to a patient safety primer available on AHRQ's Patient Safety Network. The primer explains how participants in a project in Michigan successfully reduced central line–associated bloodstream infections by employing checklists along with extensive preparatory work in safety culture and teamwork. While checklists can be used effectively to reduce the risk of errors where standardizing behavior is the goal, the primer notes that they are not appropriate for every problem. Diagnostic errors, for example, require different approaches

HIE use decreases repeat imaging in emergency departments

Using health information exchange (HIE) can decrease repeated diagnostic imaging for back and head pain, according to research supported by the Agency for Healthcare Research and Quality. Researchers analyzed cases from Memphis area emergency departments to better understand the impact of HIE on repeated x-rays, CT scans, and other radiological studies. Doctors, nurses and other clinicians working in ERs did not frequently look up results through the HIE. However, when they did use the system to obtain prior results, there was a significant reduction in repeat testing. The study suggests that more research is needed to assess strategies to encourage providers to routinely access HIEs to determine if prior test results are available.

Source: *Journal of General Internal Medicine*, February issue

Mylan sued by Aptalis in connection with Canasa ANDA

Mylan today said it has been sued by Aptalis in connection with the filing of an ANDA for Mesalamine Rectal Suppositories, 1000 mg. The product is the generic version of Canasa. Mylan said it expects to qualify for 180 days of marketing exclusivity.

EC regulator approves pneumococcal vaccine for wider use

The Wall Street Journal reported Pfizer Inc. announced Wednesday that European Commission regulators approved expanding the age range for use of its Prevenar 13 vaccine (pneumococcal polysaccharide conjugate vaccine [13-valent, adsorbed]). The pneumococcal conjugate vaccine already has approval in the EU for use in infants and children up to age 17 as well as adults ages 50 years old and older. But the EC has now approved its use for patients of all ages, including adults between age 18 and age 49, the New York City-based pharmaceutical company said in the announcement.

The AP notes that Prevenar 13, which "protects against 13 strains of pneumococcal bacteria," is the "biggest-selling vaccine in history and brings in nearly $4 billion in annual revenue." On Wednesday, the EC regulator became "the first" to approve its use for "patients at all stages of life."

According to Reuters ,the Food and Drug Administration approved the vaccine, which is called Prevnar 13 in the US, in January for use in infants, who are at least 6-weeks old, in children up to age 17, and in adults, who are 50 years of age and older. Altogether, the vaccine has approval for use in infants and children in more than 120 countries, and for use in adults age 50 and older in more than 80 countries, Pfizer noted Wednesday in its statement.

China claims GSK execs bribed Doctors

In continuing coverage, the AP reports China's police ministry said Thursday that GlaxoSmithKline employees "bribed

doctors and hospitals to prescribe medications." The ministry said in a statement that GSK employees provided free travel as "large bribes" for healthcare providers, foundations, and medical associations "to open new sales channels and increase drug revenues." GSK said last month that it "had investigated an accusation that its salespeople in China bribed doctors and found no evidence of wrongdoing."

Bloomberg News reports that some GSK executives admitted to corruption after "authorities found evidence of serious commercial bribery and tax-related crimes, the government said." Thursday's statement "marks the first time the government has given details of corruption allegations against Glaxo that surfaced last month."

Reuters reports the Ministry of Public Security's announcement did not provide details on the number of executives that were questioned as part of the investigations, nor how many admitted to crimes. Chinese authorities have said in recent months they are targeting foreign firms for price-fixing, quality controls and consumer rights.

Nanotech and spray innovations may improve drug delivery

A new nanotechnology to precisely control the size, shape and composition of drug particles, coupled with an innovative spray system, may allow for more precise and targeted delivery of drugs and biologic medications, according to researcher Joseph DeSimone of the University of North Carolina. The combination of nanoparticles with the new coating process, which is owned by Svaya Nanotechnologies and was developed by MIT professor Paula Hammond, provides "control and reproducibility," DeSimone said.

Source: In-PharmaTechnologist.com

Roche stops Diabetes trials over safety concerns

Switzerland's Roche said today it has halted a Phase III aleglitazar Ale Cardio trial after the DSMB cited safety signals and lack of efficacy. Roche said it has decided to terminate all other trials involving aleglitazar, too. The Ale Cardio trial evaluated patients with a recent acute coronary syndrome event and type 2 diabetes.

Merck, Sanofi dominate list of top 2012 vaccines

Merck and Sanofi accounted for more than half of the 15 best-selling vaccines in 2012, although the year's top spot belonged to Pfizer's Prevnar. GlaxoSmithKline scored well, too, with five vaccines on the list. Experts anticipate that Novartis will make a strong showing in 2013 with its launch of the meningitis vaccine Bexsero.

Source: Genetic Engineering & Biotechnology News

India insists drug makers get approvals by Aug. 30

After getting virtually no response to earlier requests, the Drug Controller General of India has demanded that makers of fixed dose combinations who received clearances from state licensing agencies submit their drugs for safety and efficacy approval no later than Aug. 30 or face removal of their products from the market. Earlier, the DCGI ordered state agencies to withdraw licenses from drug makers that lacked its approval, but the manufacturers received a stay from the Madras High Court.

Source: The Economic Times (India)