Drug Information Bulletin

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&
Regulatory Affairs Division (RAD), IPA

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Content

Editorial

Nutraceuticals, Food supplements, Micronutrients are flooding the market with tall claims. The gullible public is using with or prescriptions. Physicians are prescribing those products to their patients. In most of the cases without evidence of its safety, quality, and not considering drug-food interactions, drug – drug interactions. Possibility of Drug-food interaction and Drug- Drug interaction is many fold more in case of herbal food products. More research must be carried out to develop evidence of safety of such products. Though the Food Safety & Standard Act & Rules 2011 have prescribed measures for ensuring quality, it is yet to be implemented seriously and uniformly, because of weak infrastructure and insufficient manpower in major part of the country. There is overlapping between drugs and food products creating more confusion in case of applying Drugs and Cosmetics Act & Food Safety and Standard Act. Using these loopholes a drug is being marketed as food to circumvent the Drugs & Cosmetic Act and price Control. There is an urgent need to resolve these issues to protect the health of the people.

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Message: Dr. Rao V.S.V.Vadlamudi, President, IPA on the eve of a decade's service of DIB for mission "Health Care"

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In April 2017, the Drug Information Bulletin, brought out by the Drug Information Centre (DIC) of the IPA-Bengal Branch of the Indian Pharmaceutical Association completes a decade of service to the profession, which is now published jointly with the Regulatory Affairs Division (RAD) of IPA. This drug information bulletin is the first of its kind from the Indian Pharmaceutical Association, which serves the profession by providing very valuable information to a plethora of healthcare professionals that include Pharmacists, Doctors, Nurses, Health workers, NGOs as well as the public.

A very significant and important feature of this bulletin is that as a biweekly publication, it has been released on time all the time during the past decade, and the credit goes to the IPA-Bengal Branch's Drug Information Centre, and to the editor of the bulletin, Dr. Subhash C. Mandal. So significant is the contribution that about 3 years ago, 'Health Care information For All www.hifa.org' has listed the drug information centre as a supporting organization mainly because of the drug information bulletin, which disseminates quality healthcare information to all on a highly regular basis.

The Indian Pharmaceutical Association is proud of this publication and congratulates all the pharmacy professionals associated with bringing out this bulletin regularly. I take great pleasure in wishing the editorial team and the publication, on the occasion of completing a decade of service to the profession, all the best to continue to provide quality healthcare information to one and all.

V.V.S. Veerabhadra Rao

Rao V. S. V. Vadlamudi, Ph. D.
President, IPA
January 20, 2017

The U.S. Pharmacopeial (USP) Convention posted the following notices on its website

Fourteen New Revision Bulletins:
Posted January 27, 2017, official February 1, 2017

- Almotriptan Tablets
- Carbidopa and Levodopa Tablets
- Clarithromycin Extended-Release Tablets
- Chondroitin Sulfate Sodium, Shark
- Donepezil Hydrochloride Tablets
- Dutasteride
- Entecavir Tablets
- Estradiol Transdermal Systems
- Niacin Extended-Release Tablets

- Oxymorphone Hydrochloride Extended-Release Tablets
- Paroxetine Extended-Release Tablets
- Promethazine Hydrochloride Oral Solution
- Quinine Sulfate Capsules
- Theophylline Oral Solution

Ref. http://www.usp.org/usp-nf/notices

India considers formulas for cutting coronary stent prices

India's National Pharmaceutical Pricing Authority (NPPA) is considering competing proposals for reducing the price of coronary stents. Manufacturers have called for a price cap achieved by averaging hospital purchase prices, while the patient advocacy group All India Drug Action Network (AIDAN) supports a formula based on the cost to produce the devices that could cut prices by as much as half.

Ref.: The Economic Times

NICE criteria could delay NHS access to 20% of new drugs

The National Institute for Health and Care Excellence has set a new drug impact threshold criteria to better manage the budget effect of introducing new treatments endorsed for National Health Service use that could delay routine access to one in five new drugs approved. Under the new criteria, the availability of an approved drug will be delayed if it would cost the agency approximately $25 million a year or more in any of the first three financial years after its approval.

Ref.: OnMedica

Meta-analysis finds cholesterol-lowering statins may lower clotting risks

Researchers from the Leicester Diabetes Center and the University of Bristol found that use of cholesterol-lowering statins was associated with 15% to 25% reductions in the risk of developing venous thromboembolisms.

Ref.: The Lancet Haematology.

New regenerative therapy designation to be unveiled by FDA

A new designation category has been introduced by the FDA to allow drugs to be eligible for approval under a regenerative advanced therapy status. Drug makers can apply for the designation if their treatment is a human cell and tissue product, therapeutic tissue engineering product, cell therapy or combination product intended to treat, reverse, modify or cure a serious or life-threatening condition or disease, with clinical evidence indicating that it can address unmet medical needs for the condition.

Ref.: Regulatory Focus

FDA publishes guidances on drug and biologics repackaging, mixing, diluting

The FDA has issued its final guidance on repackaging drugs, which clarifies the agency's definition of repackaging and lists situations in which regulations would not be applied, such as when repackaging is done by federal facilities, state-licensed pharmacies or registered outsourcing facilities that meet the guidance's criteria. Meanwhile, a draft guidance has also been released by the agency regarding diluting, mixing and repackaging of biologics, stating that when such actions are done outside the scope of an approved biologics license application, the biological product would be considered unlicensed.

Ref.: Regulatory Focus

NPPA revises ceiling prices of 33 scheduled drugs

The national drug price regulator National Pharmaceutical Pricing Authority (NPPA) has fixed/revised ceiling prices of 33 scheduled formulations of Schedule-I under Drugs (Price Control) Amendment Order, 2017 in a notification dated 24 January 2017. Notified ceiling prices of 33 scheduled formulations of Schedule-I under Drugs (Prices Control) Amendment

Order, 2017 are cetirizine capsule, phenytoin capsule, phenytoin ER capsule, cefixime capsule, zidovudine capsule, procarbazine tablet, betamethasone gel, omeprazole tablet, phenytoin oral liquid, povidone iodine solution, omeprazole powder for injection, gentamicin injection, rifampicin oral liquid, streptomycin powder for injection, clotrimazole pessary, zidovudine + lamivudine + nevirapine tablet, permethrin lotion, omeprazole capsule, bisacodyl suppository, methylergometrine tablet, phenytoin capsule, tetanus toxoid injection, methylprednisolone injection, paracetamol injection dexamethasone injection and albendazole oral liquid. The concerned manufacturers of these formulations shall furnish quarterly return to the NPPA, in respect of production/import and sale of product in Form-III of Schedule-II of the DPCO, 2013 through IPDMS. Manufacturers in case intending to discontinue above said formulations, shall furnish information to the NPPA, in respect of discontinuation of the production and/or import of above said formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation. In case the retail price of any of the formulations is not complied with, as per instant price notification and notes specified, then the concerned manufacturer/marketing company shall be liable to deposit the overcharged amount along with the interest thereon under the provisions of the DPCO, 2013 read with the Essential Commodities Act, 1955.

Consequent to the issue of retail price of the formulations as specified in this notification, the price order(s) if any, manufacturer/marketeer issued for concerned prior to said date of notification, stand(s) superseded.

Ref. Pharmabiz

Karnataka DC registers case against e-pharmacy app for selling banned drugs

The Drug Controller of Karnataka has registered a case against Myra Medicines, an e-pharmacy app for clandestine selling of Schedule H drug and other banned medicines in the state without a valid prescription.The case was registered following a complaint from Swadesh Seva Santha, an NGO. Rahul Singh, an activist from the NGO approached the Drug Controller of Karnataka to report Myra Medicines delivering banned drugs which under the Drugs and Cosmetics Act 1940, Drugs and Cosmetics Rules 1945, the Narcotic Drugs and Psychotropic Substances Act, 1985 and FDA regulations cannot be sold to patients without a valid prescription signed by a registered medical practitioner. In order to nab Myra Medicines red-handed, members of the NGO placed various orders through their app. Myra delivered all orders including banned medicines like Corex, Schedule H medicines like Moxikind CV 625mg, Jalra M 50/500mg, Daonil 5mg and Nurokind 500 mcg without a valid prescription. The activist issued a statement that said "Such practices of delivering banned and psychotropic medicines without a valid prescription can make a drug seem bio-available and safe, when in reality it is not. Long term use of banned drugs like Corex can lead to serious kidney damage or constipation. These banned and psychotropic drugs are being sold in bulk to the youth, which has resulted in high rise of drug abuse and antibiotic microbial resistance".

Ref.: The Times of India