Drug Information Bulletin

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Content

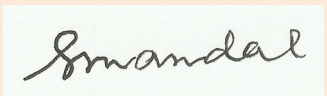
Editorial

It is my proud privilege to write the editorial of the first issue of the 12th year of the Drug Information Bulletin (DIB). This bulletin started its journey eleven years back on April 2007 under the Drug Information Centre (DIC), IPA Bengal Branch. Initially it started as a weekly bulletin and continued for eight years; thereafter this bulletin is being published on a weekly basis. Initially it was sent to the members of IPA Bengal Branch, but on request it expanded its horizon including IPA members of the entire country and now is available globally to anyone interested to receiving it. During the last four years it has been a joint publication of Drug Information Centre (DIC), IPA Bengal & Regulatory Affairs Division of IPA. It has earned several accolades to its credit from some international agencies like -Health Information for All, UK and Commonwealth Pharmaceutical Association (CPA).

On completion of each year we conduct a survey among the readers through a structured questionnaire regarding their opinion on its content regularity, its quality. We are happy we have always received encouraging results and inputs. The inputs we received have been implemented as far as possible.

The most satisfying fact is that a good number of electronic bulletins have been published during last couple of years by the individuals who were the readers of this bulletin. It has also been reported that a number of Group of Hospitals both in India and abroad are forwarding this bulletin amongst their doctors, pharmacists and nurses. Some of the pharmacy & medical colleges are keeping the printed copy of this bulletin in their library for archiving. Our reader base is growing day by day on request from health personnel and even lay persons from India and abroad.

We expect your inputs to serve you better.



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Schedule H of the Drugs and Cosmetic Rules expanded further vide G.S.R. 277(E) dtd. 23rd March 2018

In the Drugs and Cosmetics Rules, 1945, in Schedule H, after serial number 537 and the entries relating thereto, the following serial numbers and entries shall be inserted, namely,-

"538. Alclometasone 539. Beclomethasone 540. Betamethasone 541. Desonide 542. Desoximetasone 543. Dexamethasone 544. Diflorasone diacetate 545. Fluocinonide 546. Fluocinolone acetonide 547. Halobetasol propionate 548. Halometasone 549. Methylprednisone 550. Prednicarbate 551. Triamcinolone acetonide. ".

This means that products containing any of the above 14 drugs will not be dispensed from retail shop without prescription of a registered medical practitioner.

Test kits used in 'Antibody Detecting Rapid Diagnostic Tests for routine diagnosis of malaria' is banned by Govt. of India vide S.O.1352(E) dtd. 23rd March 2018

In exercise of the powers conferred by section 26A of the Drugs and Cosmetic Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale and distribution of the test kits used in 'Antibody Detecting Rapid Diagnostic Tests for routine diagnosis of malaria' with immediate effect.

RK Vats appointed as the new NPPA Chairman

The Union government appointed Rakesh Kumar Vats as the chairman of the National Pharmaceutical Pricing Authority (NPPA) with immediate effect on 7th April 2018.

The chairmanship of the Indian drug price regulator will be an additional charge for Vats, who is the additional secretary in the Ministry of Health and Family Welfare. Vats belongs to the 1986 West Bengal Indian Administrative Services (IAS) cadre.

He holds multiple positions including that of Director General (DG) of Central Government Health Scheme (CGHS), is the Chairman and Managing Director (CMD) of HLL Lifecare Limited (HLL), a public sector enterprise under Union Health Ministry that makes condoms, vaccines, medical consumables and diagnostic kits.

"The Competent Authority has approved the assignment of the additional charge of the post of Chairman, National Pharmaceutical Pricing Authority, Ministry of Chemicals and Fertilizers to Shri Rakesh Kumar Vats, IAS, Additional Secretary, Ministry of Health & Family Welfare with immediate effect and until further orders," said a statement from PK Tripathi, Secretary, Appointments Committee of the Cabinet and Establishment Officer, Department of Personnel and Training.

The post of NPPA chairman fell vacant after the government transferred Bhupendra Singh last month to head the National Authority of Chemical Weapons Convention (NACWC).

The chairman of NPPA assumed significance under Singh after the authority took steps to rein in profiteering by companies by bringing in more drug formulations under the ambit of Drug Price Control Order and capping prices of stents and knee implants.

Although healthcare activists welcomed the appointment, they were disappointed about handing over such an important charge to a bureaucrat whose hands are already tied-up with several other important responsibilities.

Source: Money Control

ASCI upheld 118 complaints against healthcare category and 5 in personal care category during Jan, 2018

The Advertising Standards Council of India (ASCI) on Friday said its Consumer Complaints Council (CCC) has upheld complaints against 171 advertisements out of 247 in January 2018 for mainly "gross exaggeration of product efficacy" and violation of acts and rules.

"In January 2018, ASCI's Consumer Complaints Council upheld complaints against 171 advertisements out of the total of 247 advertisements that were evaluated by it," a statement said.

A total of 148 advertisements were picked up by its suo moto surveillance and objections against

130 advertisements were upheld, the council said.

Of the 99 advertisements complained against by the general public or by industry members, complaints against 41 advertisements were upheld by the CCC, it said.

Amongst the 171 advertisements against which complaints were upheld, 118 belonged to healthcare, 16 to the education category, 10 to the food & beverages category, five to personal care and 22 were from the aothers' category.

"The council associates with government bodies to ensure an effective self-regulation process. We have completed a year of our association with the Ministry of AYUSH which is among top three sectors where we find a high incidence of misleading advertisements," said ASCI Secretary General Shweta Purandare.

The advertisements in the AYUSH sector claiming treatment of certain diseases in violation of the Drugs and Magic Remedies Regulations have been "a cause of concern", she said.

With support from the Ministry, the council hopes to change this scenario so that advertising is legal and ethical," Purandare said.

Gross exaggeration of product efficacy was the number one reason for upholding complaints, followed by violation of the Drugs and Magic Remedies Act and the Drugs and Cosmetics Rules, the advertisements watchdog said.

The other reasons were failure to provide substantial facts and figures to support claims and delivering advertisements which were misleading by ambiguity and or by implication, it said.

Among the various complaints, the CCC observed that a prominent FMCG drug company was providing inadequate and misleading information about its products. Similarly, a popular food brand was found to give incomplete and misleading comparison of its milkshake product.

Furthermore, an advertiser claimed to cure various diseases like heart block, cholesterol, diabetes, obesity, eye sight, Alzheimer's, kidney function, thyroid, with their product featuring an FSSAI logo, implying that the claims are approved by FSSAI. These claims, too, were found to be misleading by exaggeration, it added.

Details of upheld and recommended for action complaints

Source: Drugs Control

Safety of medicines and legal actions taken by regulatory authorities around the world

Aripiprazole risk of impulse-control disorder

The Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) have announced that the package insert for aripiprazole (Abilify®) has been updated to include the risk of impulse-control disorder as a precaution. Aripiprazole is indicated for schizophrenia, improvement of manic symptoms in patients with bipolar disorder, depression, depressed state (within certain limits) and irritability accompanying childhood autism spectrum disorder. Four cases associated with impulse-control disorder have been reported in Japan. The causal relationship was not evaluated. The company core datasheet (CCDS) has also been updated. In addition, the US Food and Drug Administration (FDA) and the Australian Therapeutic Goods Administration (TGA) have also updated package inserts to include the risk of impulse control disorder.

Reference: Revision of Precautions, MHLW/PMDA, 11 January 2018 (www.pmda.go.jp/english/)

Clozapine risk of pleurisy

The MHLW and the PMDA have announced that the package insert for clozapine (Clozaril®) has been updated to include the risk of pleurisy as a clinically significant adverse reaction. Clozapine is indicated for treatment-resistant schizophrenia. Six cases associated with pleurisy have been reported in Japan. Of these, a causal relationship could not be excluded in one case. The company core datasheet (CCDS) has also been updated.

Reference: Revision of Precautions, MHLW/PMDA, 28 November 2017 (www.pmda.go.jp/english/)

Opioid cough and cold medicines (prescription) limited use: Only for adults of 18 years of age and older

The US FDA has required that labels for prescription cough and cold medicines

containing codeine or hydrocodone are updated to include limitations of use. These products are restricted and should be used only for adults of 18 years of age and older as risks outweigh benefits when used in adolescents and children younger than 18 years of age. The FDA also requires that information about the risks of misuse, abuse, addiction, overdose, death, and slowed or difficult breathing are added to the boxed warnings for prescription cough and cold medicines containing codeine or hydrocodone. Codeine and hydrocodone are available in combination with other medicines, such as antihistamines and decongestants, in prescription medicines to treat coughs and symptoms associated with allergies or the common cold. Other non-opioid prescription and over the counter (OTC) medicines are available to treat these symptoms. The FDA has taken this action after conducting an extensive review and convening a panel of external experts.

Paracetamol (modified-release) containing products suspension in EU market

The Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) has endorsed the recommendation by the European Medicines Agency (EMA) to suspend marketing of modified- or prolonged-release products containing paracetamol. Paracetamol is widely used to relieve pain and fever in adults and children. CMDh agreed with the Agency's advice that the advantages of a longer-acting product did not outweigh the complications of managing an overdose of the medicine, since the treatment procedures for immediate release products are not appropriate for modified release paracetamol.

Reference: News and press releases, EMA, 15 December 2017 (www.ema.europa.eu)

Elected office bearers of IPA for the year 2018-2020

From L to R: Mr. Suresh Khanna-Hony. General Secretary, Mr. J. Jayaseelan-(Chairman, Industry Division, Dr. H. Mondkar -Hon. Treasurer, Dr. Subhash C. Mandal-Chairman, Regulatory Affairs Division, Dr. Alka Mukne, Editor-Pharmatimes, Mrs. Manjiri Gharat –Chairperson, Community Pharmacy Division, Dr. Rao Vadlamudi-Immediate Past President, Dr. T.V. Narayana -President, Dr. S. Vidyadhara –Chairman, Education Division, Dr. Divakar Goli -Editor-IJPS, Dr. R.N.Gupta –Chairman, Hospital Pharmacy Division(not figuring in this photograph).