It is my proud privilege to write the editorial of the first issue of the 17th year of the Drug Information Bulletin (DIB). This bulletin started its journey sixteen 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 bi-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 eight 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. On completion of each year we conduct a survey among the readers through a structured questionnaire regarding their opinion on its content regularity and its quality. We are happy we have always received encouraging results and inputs. The inputs we received have been implemented as far as possible. We are also producing their opinion in the subsequent issues.

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 their readers. 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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Pfizer issued warning on four products due to manufacturing defect

Pfizer is warning physicians and clinicians to immediately stop using four of its antibiotics i.e. Magnex, Zosyn, Magnamycin and Magnex Forte due to manufacturing issues at a contract producer. All four products treat infections, with Zosyn used to target various infections caused by bacteria including stomach infections, skin infections, pneumonia, and severe uterine infections. Magnamycin injections and Magnex Forte are also used to treat bacterial infections.

The company issued the warning because of “deviations” at a manufacturing facility operated by Astral Steritech Private Limited, according to a letter shared on Twitter by Dr. Sudhir Kumar, M.D., of Apollo Hospitals in Hyderabad.

“Whilst the manufacturer is currently investigating the matter, they have requested Pfizer, as an abundant precautionary measure and as per best practices, to temporarily suspend the sale/distribution/supply and use of the aforementioned products, pending the investigation by the manufacturer,” the company said in its letter.

Government to tighten cosmetics regulation

Testing norms for cosmetic products are being tightened as part of government plans to strengthen the regulatory mechanism for cosmetics due to incidence of sub-standard cosmetic products found to be sold in the market, which have the potential to cause face allergies and skin infection.

In a notification issued on 17 May, the Union health ministry said it plans to amend Cosmetic Rules 2020 under the Drugs and Cosmetic Act 1940 after consultations with the Drugs Technical Advisory Board. The government has given 45 days time for suggestions and feedback from the public. The government is planning to designate a Central Cosmetics Laboratory to test cosmetics samples, and may also designate any laboratory under its control for testing. In addition, manufacturers will have to keep details and record of each batch and raw materials. Records are to be maintained for three years after the expiry of each batch. Imported cosmetic products shall bear a code number as approved by the State Licensing Authority. Queries sent to the health ministry spokesperson remained unanswered. The government has further said that these rules are not applicable to the soap manufacturers, however, the procedure for testing of raw materials and the records have to be maintained by a manufacturer as approved by the Licensing Authority.

"The state Licensing Authority may issue show cause notice or suspend the license, if the authority thinks that the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act," said the official.

Furthermore, cosmetics products which are meant for export then the labels on packages or container of cosmetics shall meet the specific requirements of law of the country to which the cosmetics is to be exported and incase the product is imported, the labels on packages or containers shall bear a code number as approved by the State Licensing Authority.

Source: Livemint

Hydroxychloroquine Risk of acute febrile neutrophilic dermatosis (Sweet’s syndrome)

The MHLW and PMDA have announced that the product information for hydroxychloroquine (Plaquenil®) should be revised to add the risk of acute febrile neutrophilic dermatosis (Sweet’s syndrome). Hydroxychloroquine is indicated for the treatment of cutaneous lupus erythematosus and systemic lupus erythematosus. The MHLW and PMDA assessed six cases of adverse event reports (one domestic and five international) involving hydroxychloroquine and the event, and in four international cases a causal relationship between the medicine and event was reasonably possible.
MHLW and PMDA concluded that acute febrile neutrophilic dermatosis (Sweet’s syndrome) should be added as a clinically significant adverse reaction.

Reference: Revision of Precautions, MHLW/PMDA, 17 January 2023 (link to the source within www.pmda.go.jp/english/)

**Miltefosine: Measures to minimize the risk of ocular adverse events**

WHO is alerting healthcare professionals and regulatory authorities of the risk of ocular adverse events in people who have taken miltefosine and providing advice of measures to minimize this risk in patients exposed to miltefosine. Miltefosine is an oral antiinfective and one of the medicines with established efficacy in the treatment of some forms of leishmaniasis, a parasitic infection spread by the bite of infected female phlebotomine sandflies. Leishmaniasis can take different clinical forms, including cutaneous leishmaniasis, mucocutaneous leishmaniasis, and visceral leishmaniasis (VL). Following reports of ocular disorders following miltefosine use originating mostly from South-Asia, the WHO Advisory Committee on Safety of Medicinal Products (ACSoMP) had recommended WHO to further investigate this issue. 1 Based on the available data, the WHO ad-hoc Multidisciplinary Technical Group (MTG) considered that a causal relationship between ocular adverse events and the exposure to miltefosine is at least a reasonable possibility. The risk of ocular adverse events, such as redness of the eye, inflammation of different eye structures (keratitis, scleritis, uveitis) and visual impairment up to blindness has been observed mostly during the treatment of patients with Post-Kala-Azar Dermal Leishmaniasis (PKDL) in South Asia in both men and women, including in children under 18- year-old, and mostly beyond 28 days of treatment. No further risk factor could be identified. When the information was available, most of the cases resolved after miltefosine was withdrawn, sometimes after a symptomatic treatment was started. However, in some cases, the adverse ocular event led to permanent loss of sight. The frequency of adverse ocular events during treatment with miltefosine could not be estimated based on the available data, and the mechanism of action remains unclear. Information for health-care professionals includes: • Before starting the miltefosine treatment the history of eye disorders should be collected and an eye examination should be done as appropriate. • In case of current or past history of ocular disorder, the benefits and the risks of treating a patient with miltefosine should be carefully considered, and advice from an ophthalmologist should be sought where feasible. • All patients should be informed before starting the treatment that in case of eye problems during the treatment (e.g., red eyes, increased watering, eye pain, blurred vision) they should discontinue miltefosine and contact their healthcare professional immediately. • If ocular complications occur and a connection with miltefosine cannot be excluded, miltefosine should be discontinued immediately and an alternative treatment for leishmaniasis should be initiated if necessary. Since miltefosine has a very long half-life (>6 days), it is possible that ocular changes will not be reversible without treatment even after discontinuation of miltefosine. Therefore, an eye specialist should be consulted in such cases to avoid the possibility of permanent damage. Full information including the Guiding principles for prevention, early detection and management of eye complications in patients treated with miltefosine is provided in the link below.

Reference: Safety alert, WHO, 12 April 2023

**Isotretinoin Potential risk of blood growth hormone decreased (BGHD)**

The SFDA has released a safety signal concerning isotretinoin (oral dosage form, Roaccutane®) and the potential risk of blood growth hormone decreased (BGHD). Isotretinoin is a retinoid and derivative of vitamin A and its oral dosage form is indicated for the systemic treatment of acne. The SFDA reviewed five ICSR involving...
isotretinoin (oral dosage form) and BGHD that were reported in VigiBase. The WHO-UMC causality assessment criteria were applied, and there was one possible case (the other four cases were not assessable). Datamining indicated positive association (IC= 2.7) in VigiBase. Additionally, evidence from a multi-center study in the literature was supportive for this signal. The SFDA’s review concluded that the current available evidence might support a relationship between isotretinoin and BGHD. Health-care professionals should be aware of this potential risk and are advised to monitor any signs or symptoms in treated patients.
Reference: Safety Alerts, SFDA, 23 October 2022 (link to the source within www.sfda.gov.sa)

**Tazobactam and piperacillin Risk of haemophagocytic lymphohistiocytosis**
The MHLW and PMDA have announced that the product information for tazobactam and piperacillin (Zosyn® and the others) should be revised to add the risk of haemophagocytic lymphohistiocytosis (haemophagocytic syndrome). Tazobactam and piperacillin, a combination medicinal product for injection, is indicated for the treatment of infections mainly from gram-positive and gram-negative bacteria. The MHLW and PMDA assessed 41 cases of adverse event reports (15 domestic and 26 international) involving tazobactam and piperacillin and the event. In five domestic cases and three international cases a causal relationship between the medicine and event was reasonably possible. The MHLW and PMDA concluded that haemophagocytic lymphohistiocytosis should be added as a clinically significant adverse reaction. Health-care professionals should carefully monitor patients, and discontinue administration of this medicine and initiate appropriate measures if abnormalities such as pyrexia, rash, neurological symptoms, splenomegaly, swollen lymph nodes, cytopenia, increased LDH, hyperferritinaemia, hypertriglyceridaemia, hepatic impairment, or coagulation abnormalities are observed.
Reference: Revision of Precautions, MHLW/PMDA, 14 February 2023

**Comments from readers……..**

Dear Editor,
You are doing an excellent work and that too consistently for 16 years without any break! It is commendable. Wishing the team, the very best for continued success. The contents are short, crisp and to the point which makes it easy to read.

**Kaushik Desai**
Secretary General, International Pharmaceutical Excipients’ Council of India (IPEC India)
Secretary General, Health Foods and Dietary Supplements Association (HADSA)
ExCo, Industrial Pharmacy Section, FIP
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