



Drug Information Bulletin

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Editorial

Recently Government of India is going to amend rule 64 of the Drugs and Cosmetics Rules, 1945 by substituting clause ii of the 2nd proviso of the sub rule (2) by “(ii) in the charge of a competent person who is a registered pharmacist: Provided that the person already registered with the state Licensing Authority as competent person for the purposes of grant of license in Form 20B or Form 21 B or both prior to the coming into force of the Drugs and Cosmetics (.....Amendment) Rules, 2016, shall continue to be considered as a competent person for the said purposes.”.

This is a long pending issue to be resolved by the Government considering the public health in our country. Pharmacists are well qualified and well trained on “inventory management and storage of medicines, certainly ensure proper handling, storage, preservation and quality assurance of all medicines and medical devices. Considering this fact Drug Technical Advisory Board (DTAB) in a meeting held in August 2015 taken a resolution resulting notification vide GSR.1179 E dated 28th December 2016 by the Government for amendment of the Drugs and Cosmetics Rules, 1945. This move is welcomed by almost all of the stake holders as this will safeguard the health of the people. This will be an important milestone in Pharmacy profession.



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Allopurinol: Risk of drug-induced hypersensitivity syndrome

The Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) have announced that the package inserts for allopurinol (Zyloric® and others) have been updated to include the risk of drug induced hypersensitivity syndrome (DIHS) as a clinically significant adverse reaction. Information on cases of DIHS related type 1 diabetes mellitus (including fulminant type 1 diabetes mellitus) and ketoacidosis have also been included. Allopurinol is used for the management of hyperuricaemia in patients with gout or in hypertensive patients with hyperuricaemia. A total of two cases associated with type 1 diabetes mellitus related to DIHS have been reported in Japan. Of these, a causal relationship could not be excluded in one case.

Reference: Revision of Precautions, MHLW/PMDA, 22 November 2016 (www.pmda.go.jp/english/)

Direct-acting antivirals for hepatitis C Risk of hepatitis B reactivation

The US Food and Drug Administration (FDA) has requested that a boxed warning about the risk of hepatitis B virus (HBV) reactivation is added to the drug labels of direct-acting antivirals for hepatitis C (DDAs). This warning should also be included in the patient information leaflets or medication guides for these medicines. DAAs are used to treat chronic hepatitis C virus (HCV) infection. The FDA identified 24 cases of HBV reactivation from reports submitted to the FDA and from the published literature in HCV/HBV co-infected patients treated with DAAs from 22 November, 2013 to 18 July, 2016. Of the cases reported, two patients died and one required a liver transplant. HBV reactivation was not reported as an adverse event in the clinical trials submitted for the DAA approvals because patients with HBV co-infection were excluded from the trials. Health-care professionals are recommended to screen all patients for evidence of current

or prior HBV infection before starting treatment with DAAs, and to monitor patients using blood tests for HBV flare-ups or reactivation during treatment and post-treatment follow-up.

Reference: Drug Safety Communication, US FDA, 4 October 2016 (www.fda.gov) (See WHO Pharmaceuticals Newsletter No.3, 2016: Risk of reactivation of hepatitis B virus in Japan)

Formalin containing products Risk of shock and anaphylaxis

The MHLW and the PMDA have announced that the package inserts for formalin containing products used in dentistry have been updated to include the risk of shock and anaphylaxis as clinically significant adverse reactions. The contraindication for patients with a history of hypersensitivity to the ingredients of these products has also been included. Formalin containing products are used for disinfection of infected root canals in dentistry or sealing, pain relief, sedation and pulp capping in paediatric dentistry among others. A total of two cases associated with shock or anaphylaxis have been reported in Japan. Of these, a causal relationship could not be excluded in one case.

Reference: Revision of Precautions, MHLW/PMDA, 22 November 2016 (www.pmda.go.jp/english/)

Olanzapine Risk of urinary retention

Health Canada has updated safety information for olanzapine to strengthen warnings of the potential risk of urinary retention. The update is consistent with the safety information provided for the other atypical antipsychotic products. Olanzapine is used to treat mental disorders including schizophrenia, bipolar disorder and in some cases, depression. Health Canada has carried out a safety review investigating the potential risk of urinary retention with the use of atypical antipsychotics. At the time of the review, Health Canada had received 38 Canadian reports related to urinary retention and the use of atypical antipsychotics. These

reports, together with information from published literature indicate that most patients recovered or were recovering from the adverse effect after stopping the antipsychotic medication. In some cases, urinary retention re-occurred after the drug was re-administered, further supporting a potential link between the atypical antipsychotic and urinary retention. At the time of the review, there were 1254 international reports of urinary retention with the use of any of the atypical antipsychotics. The risk of urinary retention is mentioned in the product safety information for most of the atypical antipsychotics. However, the wording used to explain the risk of urinary retention for the approved drug olanzapine was not consistent with the evidence reviewed.

Reference: Summary Safety Review, Health Canada, 21 October 2016 (www.hc-sc.gc.ca)

Zoledronic acid Risk of Fanconi syndrome

The MHLW and the PMDA have announced that the package inserts for zoledronic acid (Zometa®, Reclast® and others) have been updated to include the risk of Fanconi syndrome as a clinically significant adverse reaction. Zoledronic acid is indicated for hypercalcaemia of malignancy, bone lesion associated with multiple myeloma or bone metastases from solid tumours and osteoporosis. A total of 11 cases associated with Fanconi syndrome have been reported in Japan. Of these, a causal relationship could not be excluded in seven cases. The company core datasheet has also been updated.

Reference: Revision of Precautions, MHLW/PMDA, 22 November 2016 (www.pmda.go.jp/english/) (See WHO Pharmaceuticals Newsletter No.4, 2015: Risk of acute phase response and renal effects in New Zealand)

Cervarix® Potential risk of GuillainBarré Syndrome: increased risk not identified

Health Canada has reviewed the potential link between Cervarix® and Guillain-Barré

Syndrome (GBS). Cervarix® is a vaccine used to protect against infection by the human papillomavirus (HPV) types 16 and 18 that cause cervical and anal cancer. At the time of the review, there were no Canadian cases of GBS reported following vaccination with Cervarix®. No cases of GBS were reported in clinical trials prior to marketing Cervarix®. After marketing, the manufacturer received 45 reports worldwide of GBS from May 2007 until November 2015. Only 10 of these reports had signs and symptoms of GBS. However, it was not possible to determine if there was a link between Cervarix® and GBS in these cases because not enough information was available for assessment, or there were other possible causes of GBS. The review did find that the number of cases of GBS reported following vaccination with Cervarix® is much lower than the number expected in the general population. Health Canada's review of all available information did not find an increased risk of GBS following vaccination with Cervarix®. Health Canada will continue to monitor the adverse effect information involving Cervarix® to identify and assess potential harms.

Reference: Summary Safety Review, Health Canada, 27 October 2016 (www.hc-sc.gc.ca) (See WHO Pharmaceuticals Newsletter No.6, 2012: Safety review shows balance of risks and benefits remains clearly positive in the United Kingdom)

FDA issues order to reclassify surgical mesh instruments

A final order has been issued by the FDA reclassifying surgical mesh instrumentation for treating female stress urinary incontinence and pelvic organ prolapse from a Class I medical device to a Class II device. The agency said reclassification of the instruments and special controls are needed due to perioperative adverse events linked to urogynecologic surgical mesh procedures, such as organ perforation and injury, nerve injury and pain and vascular injury and bleeding.

Ref. [Medtech Insight \(free-article access for SmartBrief readers\)](#)

Sanofi, Regeneron's MAA for atopic dermatitis candidate accepted for EMA review

The European Medicines Agency has accepted for review Sanofi and Regeneron Pharmaceuticals' marketing authorization application for Dupixent, or dupilumab, as a treatment for moderate to severe atopic dermatitis in adult patients who are eligible for systemic therapy. The application was based on results of three late-stage trials included in a global clinical program involving more than 2,500 patients.

Ref.: PharmaBiz.com (India)

Indian firms shifting US strategy from generics to building brands

Many top Indian pharmaceutical firms, including Sun Pharma, Dr. Reddy's, Glenmark and Aurobindo, are shifting their long-term focus from generics to branded drugs. For example, Sun bought the rights to skin cancer drug Odomzo from Novartis, Dr. Reddy's is selling a new migraine drug-device combination and Glenmark has invested in biologics to treat cancer.

Ref.: The Economic Times (India)

Health Camp at Gangasagar, West Bengal during 10.01.2017 – 15.01.2017 organized jointly by IPA, Bengal Branch & IPA Bengal Pharma & Health Care Trust



A view of IPA Health Camp at Gangasagar



A view of the base Camp of the Health camp at Gangasagar

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