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Editorial

Greetings from Drug Information Bulletin!

Medication error is the third largest contributor in case of death after Heart diseases and cancer. The magnitude may be clear with a data that about 7.7 million patients hurts every year globally. It involves economic consequences like extended hospital stays, additional treatment. Medication errors may occur due to Prescription Errors, Administration error, Transcription error and Dispensing error. There are several causes of medication errors like illegible hand written prescription, wrong dose especially in case of child below 15 years and elder above 65 years. Sometimes half of the adult dose prescribed for children inspite of calculating dose on the basis of microgram or mg per Kg body weight leading to over dosage. Other examples are use of wrong abbreviation (confusion between microgram and mg), not using zero before decimal etc. Lookalike and sound alike drugs are also a common cause of confusion leading to medication error. Besides all stakeholders pharmacists can play an important role in reducing medication error in case of Dispensing, Compounding, Patient counseling and they are doing it efficiently specially in institutional setup but high patient load per pharmacists is a deterrent here.

In our country a major portion of the drugs are being dispensed from retail medicine centre on prescription of registered medical practitioners or as self medication, where the role of Pharmacists are immense to reduce medication error. Therefore pharmacists should update themselves, serious in dispensing and be present in the community pharmacy as long as selling activities is continuing. Finally I would request all health care professionals and patients be careful about this issue as “Patient safety is everyone’s job”.

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Parallel application allowed by recent notification vide GSR 654(E) dated 24th August 2022

**MINISTRY OF HEALTH AND FAMILY WELFARE**

( Department of Health and Family Welfare)

**NOTIFICATION**

New Delhi, the 24th August, 2022

G.S.R. 654(E).—Whereas a draft of certain rules further to amend the Drugs Rules, 1945, was published, as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 382(E), dated the 23rd May, 2022, in the Gazette of India, Extraordinary, Part II, section 3, sub-section (1), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 23rd May, 2022;

And whereas, objections and suggestions received from the public on the said rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs Rules, 1945, namely:—

1. (1) These rules may be called the Drugs (Seventh Amendment) Rules, 2022.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs Rules 1945, in rule 75,—

"(a) after sub-rule (3), the following sub-rule shall be inserted, namely:—

“(3A) The application referred to in sub-rule (3) of rule 75 of these rules, and the application for grant of permission to manufacture new drug for sale or distribution under rule 80 of the New Drugs and Clinical Trials Rules, 2019 or rule 122B of these rules, as the case may be, shall be made simultaneously.”;

(b) for sub-rule (6), the following sub-rule shall be substituted, namely:—

“Where an application under this rule is for the manufacture of drug formulations falling under the purview of new drug under rule 80 of the New Drugs and Clinical Trials Rules, 2019 or rule 122B, the licence to manufacture for sale or distribution of the drugs shall be granted after approval of the drug as new drug.”.

[F. No. X.11014/2/2022-DR]

Dr. MANDEEP K BHANDARI, Jt. Secy.

**Tinidazole Risk of fixed eruption**

The National Coordination Centre – Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC) has advised the Central Drugs Standard Control Organization (CDSCO) to revise the prescribing information leaflet (PIL) for tinidazole to include fixed eruption as an adverse drug reaction.

Tinidazole is indicated for the treatment of intestinal amoebiasis, giardiasis, trichomoniasis and anaerobic infections. NCC-PvPI, IPC reviewed 71 case reports of tinidazole associated fixed eruption and a strong causal relationship between them was found.

Reference: Based on the communication from IPC, India, November 2021 (ipc.gov.in)
**Tramadol Risk of urinary retention**
The NCC-PvPI, IPC has advised the CDSCO to revise the PIL for tramadol to include urinary retention as an adverse drug reaction. Tramadol is indicated for the treatment of moderate to severe pain, diagnostic procedures and surgical pain. NCC-PvPI, IPC reviewed seven reports of tramadol-associated urinary retention and a causal relationship between them was found. Reference: Based on the communication from IPC, India, November 2021 (ipc.gov.in)

**Statins Removal of contraindication for pregnant women**
The US Food and Drug Administration (FDA) has requested revisions to the information in the prescribing information for the entire class of statin medicines about use in pregnancy. These changes include removing the contraindication against using these medicines in all pregnant patients. Statins are a class of medicines that have been used to lower low-density lipoprotein cholesterol (LDL-C) in the blood. Medicines in the statin class include atorvastatin, fluvasatin, lovasatin, pitavastatin, pravastatin, rosuvastatin, and simvasatin. It was concluded that contraindicating these drugs in all pregnant women is not appropriate because the benefits of statins may include prevention of serious or potentially fatal events in a small group of very high-risk pregnant patients. Healthcare professionals should discontinue statin therapy in most pregnant patients, or they can consider the ongoing therapeutic needs of the individual patient, particularly those at very high risk for cardiovascular events during pregnancy. Patients taking statins should notify their healthcare professionals if they become pregnant or suspect they are pregnant. Those who require statins after giving birth should not breastfeed and should use alternatives such as infant formula. Reference: Prescriber Update, Medsafe, September 2021 (link to the source within www.medsafe.govt.nz/) (See WHO Pharmaceuticals Newsletter No.3, 2020: Risk of diabetic ketoacidosis for SGLT2 inhibitors in UK.

**Empagliflozin Risk of ketoacidosis and Fournier’s gangrene New**
The Medsafe has announced that empagliflozin is associated with the risk of ketoacidosis and Fournier’s gangrene (necrotising fasciitis of the perineum). Empagliflozin is a sodium glucose co-transporter 2 (SGLT2) inhibitors and is used for the treatment of type two diabetes mellitus. The CARM received three reports of ketoacidosis and two reports of Fournier’s gangrene following initiation of empagliflozin. For the risk of ketoacidosis, healthcare professionals are advised to consider stopping empagliflozin temporarily during an acute illness, particularly if patients are unwell, febrile or vomiting and not eating. Empagliflozin should also be temporarily stopped before undergoing medical procedures or surgery. For the risk of Fournier’s gangrene, patients should be advised to seek immediate medical attention if they experience pain, tenderness, redness or swelling of the genital or perineal area, particularly with associated fever or malaise. Reference: Prescriber Update, Medsafe, September 2021 (link to the source within www.medsafe.govt.nz/) (See WHO Pharmaceuticals Newsletter No.3, 2020: Risk of diabetic ketoacidosis for SGLT2 inhibitors in UK.

**No action against Patanjali on misleading advertisements says RTI**
Repeated reminders sent by the Ministry of Ayush to Uttarakhand Drug Licensing authority to take action against Baba Ramdev’s Patanjali Ayurved for misleading advertisements of its drugs, claiming to cure diseases, have been ignored. In reply to a Right to Information (RTI) query, the Ayush ministry has claimed that it is still awaiting a report from the Uttarakhand Ayurveda and Unani services licensing authority on Patanjali and requested them to expedite the matter and submit the action taken report instantly. The ministry had earlier found that advertisements by Patanjali to promote “Lipidom”, “Livogrit”, and “Livamrit” brands of medicines were misleading and violated the Drugs and Magic Remedies (objectionable advertisement) act 1954 and Drugs and Cosmetics Act 1940. Lipidom, made by Divya Pharmacy, had advertised in February this year that it reduces cholesterol within a week,
preventing heart problems, stroke and blood pressure.

Ivigrit and Livamrit were advertised as a cure for fatty liver, liver cirrhosis and digestive system. The Ayush Ministry has also shared a trail of communication registering its objection to the false claims made by the drug manufacturer. The ministry said that no correspondence has been received from the state licensing authority and requested the director, ayurvedic and unani services to expedite the matter. Kannur-based ophthalmologist K V Babu had complained about the misleading advertisements and had also sought RTI responses on the authorities’ actions. Speaking with this newspaper, Babu, who had brought up the matter, and had filed RTI in this regard, said “even after five months, Uttarakhand SLA didn’t even bother to reply to the Government of India.” “Misleading advertising on drugs included in the scheduled drugs may inadvertently lead people to stop time tested treatment with clearly proven scientific data and resort to drugs which don’t have any proven efficacy.

The Ayush ministry had told the Parliament in July this year that misleading claims about herbal medicine in advertisements in electronic and print media have gone up, with over 10,000 objectionable promotions being reported from March 2021 to June 2022. The Advertising Standards Council of India (ASCI) received 4,885 complaints from March 2019 to February 2020 against misleading advertisements, including herbal medicines/products, in various media. From March 2020 to February 2021, 6,804 complaints about misleading advertisements were received, which went up to 10,035 complaints from March 2021 to June 2022, Ayush Minister Sarbananda Sonowal said in a written reply in the Rajya Sabha. The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and the rules encompass the prohibition of misleading advertisements and exaggerated claims of drugs and medicinal substances, including AYUSH medicines, which appear in the print and electronic media, and the government has taken note thereof.

Ref. The Indian Express

Events in recent past:

MediSAFEcon 2022, held at Kolkata on 16th September 2022, where IPA Bengal Branch was one of the partners

DISCLAIMER:
The Newsletter intends to provide updated and reliable information on medicines and other related issues in an attempt to equip healthcare professionals to take informed decision in recommending medicines to the patients. However, they are encouraged to validate the contents. None of the people associated with the publication of the Newsletter nor the organization shall be responsible for any liability for any damage incurred as a result of use of contents of this publication. The brand names of medicines, if mentioned, are for illustration only and the Newsletter does not endorse them.