Editorial

Greetings from Drug Information Bulletin!

Recently Bihar Government has implemented the Pharmacy Practice (Amendment) Regulation (PPR)-2021 vide a notification dated 6.3.2023. This is a welcoming step as a few of the states has taken the same step.

Pharmacy Council of India has notified Pharmacy Practice Regulation (PPR) in the year of 2015, and the same has been amended in the year of 2021 but unfortunately a few states have taken necessary steps to implement the same. Through this regulation they have prescribed the Rights and responsibility of the registered pharmacists in details. They also framed the Pharmacy cadre structure for making the pharmacy service suitable in the present perspective of the socio economic situation, but there is not much improvement of Pharmacy practice in India. Though number of pharmacy colleges increased many fold and huge number of pharmacists are coming out every year most of the retail pharmacies are running without the service of a pharmacists leading to rampant misuse of medicines resulting adverse drug reactions, antimicrobial resistance etc. which are threats to the patient safety. These are due to non compliance to the relevant legislation of our country in place. It is the high time for the implementing authorities and pharmacists at large work hard for implementation of the concerned legislation. IPA is trying hard in this direction and there are a few successes in there Endeavour. Hope a consorted effort will give more success.

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New drug: Elasomeran/imelasomeran for prevention of COVID-19

Approved indication: prevention of COVID-19

Spikevax bivalent original/Omicron (Moderna) multi-dose vials containing 0.1 mg/mL

Vaccines against SARS-CoV-2 became available during 2021. However, in November 2021 the Omicron variant of the virus emerged and became the dominant strain. Several sub-lineages of the Omicron variant subsequently appeared. The vaccines developed earlier in the pandemic were less effective against Omicron. Vaccine manufacturers have therefore needed to develop new products to improve protection. Clinical trials are ongoing, but data have been provided to regulatory agencies to enable emergency or provisional use of the new products. The provisional approval of elasomeran/imelasomeran in Australia is for use as a booster dose in adults.

Elasomeran was the main component of a messenger RNA (mRNA) vaccine approved in 2021. Imelasomeran is also a mRNA vaccine, but is based on the spike protein of Omicron lineages. The two vaccines are enclosed in lipid nanoparticles to enable them to enter cells after intramuscular injection. Each 0.5 mL dose contains 25 micrograms of elasomeran and 25 micrograms of imelasomeran. After entry into cells the vaccines’ mRNA stimulates the production of spike proteins. This generates an immune response which may prevent subsequent infection with SARS-CoV-2.

At present, the evidence for this bivalent vaccine is based on its immunogenicity in adults. One trial is studying people who have previously received two doses and a booster of elasomeran. A group of 437 adults was given the bivalent vaccine and 377 were given another dose of elasomeran as their second booster. By 29 days after these boosters, antibody titres against SARS-CoV-2 had increased in both groups. There was no difference between the bivalent vaccine and elasomeran alone in stimulating antibodies against an ancestral variant of the virus. When considering the Omicron variant, the response was greater in the group given the bivalent vaccines (geometric mean ratio 1.7).

Most people will have adverse effects to a booster of elasomeran or the bivalent vaccine. These are usually mild or moderate and resolve in a few days. Approximately 80% will have pain at the injection site. There may also be swelling at the injection site and axilla. Erythema was more frequent with the bivalent vaccine (6.9% vs 3.7%). Very common systemic effects include headache, fatigue, myalgia and arthralgia.

While the combination of elasomeran and imelasomeran produces neutralising antibodies, the effectiveness of this bivalent booster is yet to be confirmed. The ongoing study was not designed to evaluate effectiveness, but it found that after a median follow-up of 43 days, 3.2% of those given the bivalent vaccine were infected by SARS-CoV-2 compared with 1.9% of the elasomeran group after a median of 57 days. No participants needed hospital admission. While the adverse effects will probably resemble those of elasomeran, the safety data are limited in size and duration. Reporting adverse events, following a bivalent booster dose, to the Therapeutic Goods Administration is therefore particularly important.

Adverse Drug Reactions of some common drugs:

Cephalosporins Risk of fixed drug eruption.

The Central Drugs Standard Control Organization (CDSCO) has approved the recommendation from the National Coordination Centre – Pharmacovigilance Programme of India (NCC-PvPI), Indian Pharmacopoeia Commission (IPC) to revise the prescribing information leaflet (PIL) for cephalosporins to include fixed drug eruption as an adverse drug reaction. Cephalosporins are a group of antibiotics that belong to a beta-lactam class, indicated to manage a wide range of infections from gram-positive and gram-negative bacteria. The NCC-PvPI, IPC reviewed 203 Individual Case Safety Reports (ICSRs) of cephalosporin associated fixed drug eruption and a causal relationship between them was found.

Reference: Based on the communication from IPC, India, October 2022 (link to the source within ipc.gov.in)

Haloperidol Risk of cogwheel rigidity.
The CDSCO has approved the recommendation from the NCC-PvPI, IPC to revise the PIL for haloperidol to include cogwheel rigidity as an adverse drug reaction. Haloperidol is indicated for the treatment of chronic schizophrenia. The NCC-PvPI, IPC reviewed 11 ICSRs of haloperidol associated cogwheel rigidity and a causal relationship between them was found.
Reference: Based on the communication from IPC, India, October 2022 (link to the source within ipc.gov.in)

**Olanzapine Risk of hyponatraemia.**
The CDSCO has approved the recommendation from the NCC-PvPI, IPC to revise the PIL for olanzapine to include hyponatraemia as an adverse drug reaction. Olanzapine is indicated for the treatment of schizophrenia in adult patients, rapid control of agitation and disturbed behaviour in patients. The NCC-PvPI, IPC reviewed 20 ICSRs of olanzapine associated hyponatraemia and a causal relationship between them was found.
Reference: Based on the communication from IPC, India, October 2022 (link to the source within ipc.gov.in)

**Remdesivir Risk of sinus bradycardia.**
The CDSCO has approved the recommendation from the NCC-PvPI, IPC to revise the PIL for remdesivir to include sinus bradycardia as an adverse drug reaction. Remdesivir is indicated for the treatment of suspected or laboratory confirmed corona virus disease 2019 (COVID-19) in adults and children hospitalised with moderate to severe disease. The NCC-PvPI, IPC reviewed 11 ICSRs of remdesivir associated sinus bradycardia and a causal relationship between them was found.
Reference: Based on the communication from IPC, India, October 2022 (link to the source within ipc.gov.in) (See also WHO Pharmaceuticals Newsletter No.1 2022: Remdesivir and Potential risk of sinus bradycardia in Canada, No.4, 2021 in Europe)

**Tigecycline Risk of coagulopathy.**
The CDSCO has approved the recommendation from the NCC-PvPI, IPC to revise the PIL for tigecycline to include coagulopathy as an adverse drug reaction. Tigecycline is indicated for the treatment of skin and abdominal infections. The NCC-PvPI, IPC reviewed three ICSRs of tigecycline associated coagulopathy and a causal relationship between them was found.
Reference: Based on the communication from IPC, India, October 2022 (link to the source within ipc.gov.in)

**Minoxidil Risk of folliculitis.**
The NCC-PvPI, IPC has recommended the CDSCO to revise the prescribing information leaflet (PIL) for minoxidil to include folliculitis as an adverse drug reaction. The recommendation is under consideration of the CDSCO. Minoxidil is indicated for the treatment of alopecia (male pattern baldness) in men. The NCC-PvPI, IPC reviewed 17 ICSRs of minoxidil associated folliculitis and a causal relationship between them was found.
Reference: Based on the communication from IPC, India, October 2022 (link to the source within ipc.gov.in)

**Itraconazole Risk of hypokalaemia.**
The MHLW and PMDA have announced that the product information for itraconazole (oral dosage form and injections) should be revised to include the risk of hypokalaemia. Itraconazole is indicated for the treatment of fungal infection. The MHLW and PMDA reviewed three cases of hypokalaemia reported domestically, in which a causal relationship between the drug and event was reasonably possible. The MHLW and PMDA concluded that hypokalaemia should be added as a clinically significant adverse reaction. Health-care professionals are advised to perform blood electrolyte tests periodically irrespective of particular conditions for use (e.g., dosage and period of administration).
Reference: Revision of Precautions, MHLW/PMDA, 12 October 2022 (link to the source within www.pmda.go.jp/english/)

**Novo Nordisk to slash U.S. insulin prices by up to 75%, following move by Eli Lilly**
Novo Nordisk, one of the world’s biggest insulin makers, will cut the list price of its NovoLog insulin by 75% and the prices for Levemir and Novolin by 65%, the company said in a press release. The price changes will go into effect on Jan. 1, 2024. They will cover insulins that come in vials and injection pens.
NovoLog’s list price will fall to $139.71 from $558.83 for a pack of five injection pens. For a vial, the price will decrease to $72.34 from $289.36.

The company also said it plans to reduce the list price of its unbranded insulin products to match the lowered price of each respective branded insulin.

“We have been working to develop a sustainable path forward that balances patient affordability, market dynamics, and evolving policy changes,” Steve Albers, Novo Nordisk’s senior vice president of market access and public affairs, said in the release. “Novo Nordisk remains committed to ensuring patients living with diabetes can afford our insulins, a responsibility we take seriously.”

A Novo Nordisk spokesperson also told that the price cuts “have been in development for many months, but due to increased stakeholder interest, we accelerated to announce now.”

Novo Nordisk’s actions were first reported by the Wall Street Journal.

The announcement comes two weeks after drug maker Eli Lilly said it would cut the prices of its most commonly prescribed insulins by 70% and expand a $35 monthly cap on patients’ out-of-pocket costs starting in the fourth quarter. Novo Nordisk, Lilly and Sanofi control over 90% of the global insulin market.

The move also comes after insulin manufacturers faced years of pressure from lawmakers to make the lifesaving hormone more affordable for people with diabetes.

The Inflation Reduction Act capped monthly insulin costs for Medicare beneficiaries at $35 per monthly prescription, but it fell short of providing protection to diabetes patients who are covered by private insurance.

Ref. CNBC

Reader’s Comment…………..

Dear Dr Mandal,

Thank you very much for publishing the letter of National Medical Commission notification about opening of AMC (Adverse Drug Reactions Monitoring Centre) in each medical Colleges of India, under PVPI Programme of Indian Pharmacopeia Commission. This is the right step taken by National Medical Commission.

Though the reporting of ADR is a most important tool to save the masses by taking appropriate steps by IPC and DCGI but it is noted that the Pharmacovigilance Associates of AMC in many places are not getting proper cooperation in reporting of ADRs by many of Physicians. Hence it is required that National Medical Commission has to issue guidelines that doctors of all departments of all hospitals have to cooperate with Pharmacovigilance Associates and have to report each case of ADR on observation. As well as Indian Pharmacopeia Commission has to appoint Pharmacovigilance Associate in all Medical College Hospital within 1-2 months for its proper functioning.

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&
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