Editorial

Greetings on the eve of World Patient Safety Day!

The National Coordination Committee (NCC) of Pharmacovigilance Programme of India (PvPI) has decided to celebrate the Pharmacovigilance week starting from the World Patient Safety Day (WPSD) for one week, 17-23 September 2021 and chalked out a weeklong programme with a theme “Pharmacovigilance: Step towards Patient Safety”. This theme is aptly chosen by WHO keeping in mind the fact that “approximately 810 women die every day from preventable causes related to pregnancy and childbirth. In addition, around 6700 newborns die every day, amounting to 47% of all under-5 deaths. Moreover, about 2 million babies are stillborn every year, with over 40% occurring during labour. Most of these incidents are avoidable through the provision of safe and quality care by skilled health professionals working in supportive environments. This can only be achieved through the engagement of all stakeholders and the adoption of comprehensive health systems and community-based approaches.”

The Pharmacy Council of India has requested all the pharmacy institutions to celebrate this week in a grand manner for generating awareness about Patient safety and Pharmacovigilance among all stakeholders. It is expected that all stakeholders will celebrate this week meaningfully.

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New Drug: Elasomeran for prevention of COVID-19
Approved indication: prevention of COVID-19
Spikevax (Moderna)
5 mL multidose vials containing 0.2 mg/mL

Elasomeran is the fourth COVID-19 vaccine received provisional approval from TGA on 3rd September 2021 in Australia. It is indicated to prevent COVID-19 in individuals 12 years old and over.

Like the BNT162b2 COVID-19 vaccine (made by Pfizer), elasomeran is a messenger RNA (mRNA-1273) vaccine. The RNA encodes for a modified form of the spike protein of the coronavirus. It is encapsulated in lipid nanoparticles to enable the RNA to be taken into cells after intramuscular injection. The cells produce the spike protein which then induces an immune response which includes neutralising antibodies.

Preliminary investigations, including some patients over the age of 56 years, established the dose regimen to be used in a randomised phase III trial. This was two doses of 100 micrograms of mRNA (0.5 mL) given 28 days apart.

The ongoing phase III trial in the USA has reported its results for people followed up for a median of 63 days after the second injection. The per-protocol analysis included 14,134 adults who received the two doses of the vaccine and 14,073 who received a saline placebo. Efficacy was assessed by the occurrence of symptomatic COVID-19 at least 14 days after the second injection. Eleven cases occurred in the vaccine group compared to 185 cases in the placebo group. This gives a vaccine efficacy of 94.1% for the prevention of symptomatic infection. The efficacy was similar across all age groups. Elasomeran had an efficacy of 100% against severe infection as the 30 cases that had severe COVID-19, including one death, were all in the placebo group.

Adverse reactions at the injection site were more frequent with the vaccine than with placebo (88.6% vs 18.8% after the second injection). These effects included pain, tenderness, erythema and induration and may have a delayed onset. There have been cases of anaphylaxis, so people need to be observed after vaccination. More common adverse reactions include fatigue, headache, myalgia and arthralgia. The frequency and severity of these adverse effects was greater after the second dose of vaccine. They persist for an average of three days. Myocarditis and pericarditis may be rare adverse effects.

Elasomeran has to be stored between −25 °C and −15 °C. Thawed vials should be stored at 2 °C to 8 °C until used. Each multidose vial contains enough vaccine for 10 doses (0.5 mL). Dilution is not required. The deltoid muscle is the preferred site for injection.

Like all the vaccines against COVID-19, the efficacy and safety data for elasomeran are incomplete. For example, children and pregnant women were not included in the phase III trial and there was a limited number of immunocompromised patients. The efficacy against different viral strains and the duration of protection is unknown. A small study suggests that elasomeran produces higher antibody concentrations than the BNT162b2 vaccine in people over 50 years old.

The Transparency Score is explained in New drugs: transparency, Vol 37 No 1, Aust Prescr 201 4; 37:27.

At the time the comment was prepared, information about this drug was available on the websites of the Food and Drug Administration in the USA, the European Medicines Agency and the Therapeutic Goods Administration.

References

**Status in India:** Moderna Covid-19 vaccine has got emergency approval from CDSCO in India for use above 18, which may be available for use very soon.

**5 Covid Deaths in 4 Months despite Full Jabs, 4 AEFI-Forced Hospitalisations**

Five fully vaccinated people died of Covid from March to June in India, according to a Right to Information (RTI) response from the Centre. In the same period, another four patients were to be hospitalised following Adverse Events Following Immunization (AEFI). The Union Ministry of Health made this submission to an RTI application by this correspondent seeking data on Covid deaths post completion of both vaccine doses.

"Based on the information from Adverse Events Following Immunization (AEFI) reports received from districts, four patients were to be hospitalised and five died who tested positive following receipt of both vaccines,” the health ministry said in its response.

Notably, the health ministry said that the immunisation section does not maintain data and therefore no information is available to furnish regarding the details of healthcare workers who tested Covid positive or succumbed due to the infection after receiving vaccines.

After analysing the data between April and August, the ministry on Thursday said that one vaccine dose alone is 96.6% effective in preventing Covid-19 deaths while two doses are 97.5% effective.

"No vaccine can be 100% efficacious. The response to the vaccine can vary from person to person and whether a person has taken both doses. The maximal effect is seen after at least 2 weeks post the second dose. Age, comorbidities and immuno-compromised status are also responsible and play a role in how vaccines will elicit a protective immune response in an individual. The effect of the vaccine on a young and healthy body with that to a 70-year-old with comorbidities will be different. That's why it is said that even after vaccine one needs to continue COVID appropriate behaviour till this pandemic lasts," said Dr Neeraj Nischal, Associate Professor, Medicine at AIIMS.

The doctor further explained how the vaccine works differently from individual to individual. “Such people remain at a higher risk of testing positive even after receiving both doses. The effect of vaccines on a young and healthy body with that of a 70-year-old with co-morbidities will be different. That's why it is advised that even after vaccines, one should take precautions,” the senior doctor added.

According to a senior AIIMS doctor, vaccines are not 100% effective. He added co-morbidities and other factors are responsible for how the vaccine works on a human body. Such people remain at higher risks for testing positive.

Source: The New Indian Express

**Fluoroquinolones Risk of heart valve regurgitation**

The Health Sciences Authority (HSA) has announced that the use of systemic fluoroquinolones are associated with a small increased risk of heart valve regurgitation. Fluoroquinolones are indicated to treat infections such as acute sinusitis and acute bronchitis. There are seven systemic fluoroquinolones used in Singapore: ciprofloxacin, ofloxacin, norfloxacin, lomefloxacin, levofloxacin, moxifloxacin and pefloxacin. Fluoroquinolones are known to increase the risk of collagen related disorders such as tendonitis, tendon rupture, and aortic aneurysm and dissection. In September 2020, the EMA concluded that fluoroquinolone use may increase the risk of heart valve regurgitation, and as a result the EMA recommended that the existing warning on aortic aneurysm and dissection in the package inserts of systemic and inhaled fluoroquinolone-containing products should be expanded to include heart valve regurgitation. The HSA has not received any local reports of heart valve related disorders.
associated with fluoroquinolone. Health-care professionals are advised to take into consideration the risk when prescribing systemic fluoroquinolones and the availability of other therapeutic options for patients with preexisting risk factors such as heart valve diseases, connective tissue disorders, hypertension or rheumatoid arthritis.

Reference: Product Safety Alerts, HSA, 12 May 2021 (www.hsa.gov.sg/) (See also WHO Pharmaceuticals Newsletter No.1, 2021: Risk of heart valve regurgitation in UK; No.2, 2020: Risk of aortic aneurysm and dissection in Australia; No.6, 2019: Risk of tendon disorders, peripheral neuropathy and psychiatric symptoms in Japan)

**Polyethylene glycol (PEG) laxatives and starch-based thickeners Potential interaction: risk of aspiration**

The MHRA has announced that it has requested that the manufacturers of Polyethylene glycol (PEG) laxatives to update the summary of product characteristics (SmPC) and the patient information leaflet (PIL) to include information about a potential interaction with starch based thickeners that can increase the risk of aspiration in patients with dysphagia. PEG laxative products are used to treat constipation through an osmotic effect. Thickeners are used to thicken liquids taken by patients with dysphagia, including elderly and those who have trouble swallowing. There are two main types of thickening agents: starch- and gum-based. Adding a PEG-based laxative to a liquid that has been thickened with a starch-based thickener may counteract the thickening action. Constipation and dysphagia coexist more commonly in the elderly and in those with swallowing difficulties. Although the MHRA is not aware of any cases of this potential interaction in the UK, an institute in Canada has issued a safety bulletin discussing a potential harmful interaction between PEG laxative and starch-based thickeners.

Reference: Drug Safety Update, MHRA, 27 April 2021 (www.gov.uk/mhra)

**Forthcoming Events:**

### THE INDIAN PHARMACEUTICAL ASSOCIATION (BENGAL BRANCH)

**ORGANIZING**

**POSTER DESIGNING COMPETITION**

**“WORLD PHARMACISTS DAY 2021”**

**“PHARMACY: ALWAYS TRUSTED FOR YOUR HEALTH”**

All Pharmacy Professionals and Pharmacy student studying in an institution approved by PCI in West Bengal

**CHAMPION: First Runner-up and Second Runner-up will be recognized accordingly with CERTIFICATE and PRIZE MONEY**

**Eligibility:** Pharmacy student studying in an institution approved by PCI in West Bengal. The essay should not be more than 2000 words. Email the poster in a JPEG format with your name, contact number, institution name, and other details.

**End Date:** 25th September 2021

**For further information:** Call 8890 2506 552

### THE INDIAN PHARMACEUTICAL ASSOCIATION (BENGAL BRANCH)

**ORGANIZING**

**ESSAY WRITING COMPETITION**

**ON THE THEME: “WORLD PHARMACISTS DAY 2021”**

**“PHARMACY: ALWAYS TRUSTED FOR YOUR HEALTH”**

Eligibility: Pharmacy student studying in an institution approved by PCI in West Bengal. The essay should not be more than 2000 words.

**Email the essay to lipc@ipo.gov.in**

**End Date:** 25th September 2021

**For further information:**

**Indian Pharmacopoeia Commission**

**National Pharmacopoeia Programme of India (PnP), Ministry of Health and Family Welfare, Govt. of India, Sector-23, Raj Nagar, Ghaziabad - 201002**

**Pharmacopoeia Programme of India (PnP)**

PnP monitors the safety profile of medicinal products used in India. It sets the national and international standards of medicinal products, and it is being improved by adding a National Pharmacopoeial Reference Database (NPDR) and a platform for communication and knowledge exchange to the benefit of all stakeholders. It includes patient safety, drug safety, and a wide range of medicines.

**National Pharmacopoeia Week**

**17th - 23rd September, 2021**

**Let’s all celebrate!!!**

**National Pharmacopoeia Week**

**Special focus on:**

**National Pharmacopoeia Week**

**Special focus on:**

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