Greetings from Drug Information Bulletin!

It is my proud privilege to write the editorial of the first issue of the 16th year of the Drug Information Bulletin (DIB). This bulletin started its journey fifteen 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 five 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 like -Health Information for All, UK and Commonwealth Pharmaceutical Association (CPA). On completion of each year we conduct a survey among the readers through a structured questionnaire regarding their opinion on its content regularity, its quality. We are happy we have always received encouraging results and inputs. The inputs we received have been implemented as far as possible. 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 archiving. 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.

Greetings to you all.

Dr. Subhash C. Mandal
Editor
E mail: subhash.mandaldr@gmail.com
Mob. 9830136291
New Drug: SARS-CoV-2 rS (NVX-CoV-2373) vaccine for prevention of COVID-19
Approved indication: prevention of COVID-19
Nuvaxovid (Biocelect)
multidose vials containing 5 microgram
SARS-CoV-2 spike protein in adjuvanted suspension
SARS-CoV-2 rS, commonly referred to as Novavax, is the fifth vaccine to be provisionally approved in Australia for the prevention of COVID-19 in people 18 years of age and over. Its mechanism of action differs from that of the other vaccines. This vaccine is based on a genetically engineered form of the SARS-CoV-2 spike protein. It also contains an adjuvant to enhance the immune response of B and T cells.
The vaccine is supplied in multidose vials that should be stored at 2–8 °C. Each vial contains ten doses of 0.5 mL. The vaccine is given by intramuscular injection, with a second dose three weeks later.
A phase II trial took place in South Africa around the time the Beta variant of the virus emerged. This placebo-controlled trial randomised 4406 healthy adults, but, as approximately 30% of them already had antibodies against SARS-CoV-2, efficacy was assessed in 2684 seronegative participants who received two doses of the vaccine. Symptomatic COVID-19 developed in 1.1% (15/1357) of the vaccine group and 2.2% (29/1327) of the placebo group.
A phase III trial in the United Kingdom randomised 15,187 adults to receive the vaccine or a placebo. Efficacy was assessed in 14,039 participants who were seronegative and received two doses. Symptomatic infection occurred, at least seven days after the second dose, in 0.14% (10/7020) of the vaccine group and 1.4% (96/7019) of the placebo group. Vaccine efficacy was calculated to be 89.7%. None of the fully vaccinated participants required hospital admission.
Within the UK trial, a group of 431 participants was injected with influenza vaccine at the same time as their first dose of SARS-CoV-2 rS or placebo. Although there was no difference in the immune response to the influenza vaccine, there was a reduced response to the SARS-CoV-2 rS vaccine. Symptomatic COVID-19 developed in 1% (2/191) of the vaccine group and 4% (8/195) of the placebo group. Vaccine efficacy against COVID-19 was calculated to be 74.8% overall and 87.5% in participants under 65 years of age.
A phase III trial in North America randomised 29,949 adults. Two doses of vaccine were given to 17,312 seronegative participants and 8140 received injections of placebo. After a median follow-up of three months, there were 14 cases (0.1%) of COVID-19 in the vaccinated group and 63 cases (0.8%) in the placebo group. Vaccine efficacy was calculated to be 90.4%. All cases of COVID-19 in the vaccinated group were mild.
In the phase III trials, adverse reactions were more frequent following vaccination than in the placebo groups. Reactions were more common after the second dose, in younger people and in participants who received simultaneous influenza vaccine. The most frequent reactions were injection-site tenderness (75%) or pain (62%). Systemic adverse effects reported in the trials included headache, arthralgia, myalgia and fatigue. The adverse reactions lasted for an average of one or two days. Uncommon adverse events include hypertension and myocarditis. As anaphylaxis is a potential adverse reaction, patients should be observed for at least 15 minutes after being vaccinated.
When SARS-CoV-2 rS was evaluated, the median duration of follow-up after the second dose was 70 days. The phase III trials began before the current viral variants of concern emerged. Information about the efficacy and safety of this vaccine will therefore continue to evolve. At present, it is not approved for use in children or for booster doses. In theory this vaccine could be given in pregnancy but there are currently more data about using other COVID-19 vaccines during pregnancy and lactation.
References:


**Status in India:**
In December 28, 2021, Drugs Controller General of India (DCGI) has issued Emergency Use Authorization (EUA) for Covovax /Recombinant Spike Protein of SARS-CoV-2 Virus 5 mcg to induce immunity against SARS-CoV-2 to prevent COVID-19 for adults 18 years old and above.

In March 2022 the Drugs Controller General of India (DCGI) has issued permission for restricted use in emergency situation for Covovax for active immunization to prevent COVID-19 caused by SARS-Cov-2 in individuals 12 years of age and older.

This COVID vaccine, also known as NVX-CoV2373, is manufactured and marketed in India by the Serum Institute of India (SII) under the brand name Covovax and is the first protein-based vaccine authorized for use in this age group in India. As per the industry source the price of Covovax is Rs. 900 per dose+ GST.

**Patna High Court directs State Govt to remove all members including the President of the Bihar Pharmacy Council**
While hearing a PIL filed by petitioner Uma Shankar Sharma, a division Bench of Justice Sanjoy Karol and Justice S Kumar ordered state Govt. to appoint any ex-officio member as the Registrar at the earliest.

The Court directed that “....the State must exercise its power under section 45 (5) of the Pharmacy Act and have a proper inquiry conducted with regard to the management and affairs of the council. In the attending circumstances, we would have directed the State to exercise such power, but leave it to their wisdom to do so immediately.”

The court has directed -
1. the Director General of Police, Bihar to ensure that investigation with respect to FIRs is completed, if not already so done, and the report submitted in accordance with law at the earliest. However this must positively be done within a period of four weeks. The court further clarified that pendency of any proceedings, save and expect, for any direction issued by the Supreme Court of India, shall not come in the way of early completion of such enquiry and investigation.

2. the Superintendent of Police, Vigilance Bureau, Bihar must also complete the investigation based on the information finished by the petitioner and the report submitted positively within four weeks.

3. the Principal Secretary of the State Health Department to immediately appoint a new officer to the post of Registrar.

The Additional Secretary, Health Dept., Govt. of Bihar, The Director general of Police, Bihar, Superintendent of Police Vigilance Bureau, Patna must submit their report before 23.06.2022 the next date of hearing.

This matter was also pursued with the Bihar State Govt. in several levels by the Bihar Branch of Indian Pharmaceutical Association since past few years.

Ref. Judgments in the matter of Civil Writ Jurisdiction Case No. 20704 of 2021

**Roche Pharma launches PHESGO in India for the treatment of HER-2 positive breast cancer**
Roche Pharma announced the launch of PHESGO, the fixed dose combination of two monoclonal antibodies in oncology for the treatment of HER-2 positive breast cancer now available in India. The drug combines two proven monoclonal antibodies- Pertuzumab and Trastuzumab with Hyaluronidase in a single vial for subcutaneous administration. The subcutaneous injection in combination with intravenous (IV) chemotherapy, for the treatment of early and metastatic HER-2 positive breast cancer.
PHESGO is the first approved by the USFDA in June 2020 and by European Medicines Agency (EMA) in December 2020. In India OHESGO was approved by DCGI in October 2021 and the import license was granted in January 2022.

COVID-19 vaccine NRVV Ad26 (JNJ 78436735) 1. Risk of venous thromboembolism (VTE)

The PRAC has recommended that thromboembolism (VTE) should be listed as a rare side effect in the product information for COVID-19 vaccine NRVV Ad26 (JNJ 78436735) (COVID-19 vaccine Janssen®). VTE is a condition in which a blood clot forms in a deep vein, usually in a leg, arm or groin, and may travel to the lungs causing a blockage of the blood supply, with possible life-threatening consequences. COVID-19 vaccine NRVV Ad26 (JNJ 78436735) is indicated for preventing COVID-19. The PRAC reviewed data form two large clinical studies and post marketing surveillance and concluded that there is a possible link to rare cases of VTE with COVID-19 vaccine NRVV Ad26 (JNJ 78436735). The PRAC has also recommended to provide a warning to raise awareness among healthcare professionals and people taking the vaccine, especially those who may have an increased risk of VTE, and to assess a potential diagnosis of thrombosis with thrombocytopenia syndrome (TTS) when signs are present within three weeks after vaccination. Reference: Patients and carers, EMA, 1 October 2021 (link to the source within www.ema.europa.eu)

2. Risk of immune thrombocytopenia (ITP) Europe. The PRAC has recommended that dizziness and tinnitus should be listed as adverse reactions in the product information of COVID19 vaccine NRVV Ad26 (JNJ 78436735) (COVID-19 vaccine Janssen®). Tinnitus is ringing or other noises in one or both ears. The PRAC assessed the available evidence including cases of dizziness identified in spontaneous reports and cases of tinnitus identified in clinical trials and spontaneous reports and concluded that cases of dizziness and tinnitus are linked to the administration of COVID-19 vaccine NRVV Ad26 (JNJ 78436735). Reference: Patients and carers, EMA, 6 August 2021 (link to the source within www.ema.europa.eu)

Comment on an article under heading “New Drug: Molnupiravir for COVID-19” in the last issue

There are more than 15 Indian manufacturers with the cost ranging from Rs. 1400 to Rs. 4000 for 40 capsules of 200 mg. Some of the manufacturers’ are-Torrent, Cipla, Mylan, Sun Pharma, Hetero, Dr. Reddys, Natco etc. Readers are advised to check the products and the prices before purchasing. All products are cheaper than the originator product thus demonstrating availability of affordable medicines to the population of India (One 5 day course with Indian product cost is around 18.77 $ whereas it is 700 $ in USA).

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.