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Editorial

Merry Christmas Greetings from Drug Information

Recently Drugs Controller General (DCGI) approved restricted use in emergencies for people aged 18 and above to the intranasal vaccine for Covid-19 in India for heterologous booster doses. Heterologous booster dose studies were conducted for safety and immunogenicity in 875 subjects with BBV154 intranasal vaccine, administered post 2 doses of the two commonly administered Covid-19 vaccines. This vaccine has been developed by Bharat Biotech a biotechnology firm supported by Dept. of Biotechnology (DBT) and Biotechnology Industry Research Assistance Council (BIRAC)-a nonprofit, Public sector Enterprises, set up by Department of Biotechnology, Government of India. This vaccine has been developed using indigenous technology and an example of success of a joint venture of a private manufacturer with Govt. research organization. Bharat Biotech has launched this vaccine under brand name iNCOVACC and is available in co win portal for vaccination. Earlier two Covid vaccines - Covaxin and ZyCov-D was developed in India using indigenous technology which shows the strength of Indian company to innovate new product. Expecting Indian pharma industry will be transformed from manufacturing to innovation hub in near future.

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Health Secretary, Government of India issued advisory to states on recent upsurge of Covid in other countries

Dear Colleague,

India with its focus on five-fold strategy of test-track-treat-vaccination and adherence to COVID Appropriate Behavior has been able to restrict the transmission of Covid-19 virus and is having around twelve hundred cases on a weekly basis. Public Health challenge of Covid-19 still persists around the world with around thirty-five lakh cases reported weekly.

2. The ‘Operational Guidelines for Revised Surveillance Strategy in context of COVID-19’ issued by Union Ministry of Health & Family Welfare in June, 2022 calls for early detection, isolation, testing, and timely management of suspected and confirmed cases to detect and contain outbreaks of new SARS-CoV-2 variants. Therefore, monitoring the trends of existing variants is of crucial importance.

3. In view of the sudden spurt of cases being witnessed in Japan, United States of America, Republic of Korea, Brazil and China, it is essential to gear up the whole genome sequencing of positive case samples to track the variants through Indian SARS-CoV-2 Genomics Consortium (INSACOG) network. Such an exercise will enable timely detection of newer variants, if any, circulating in the country and will facilitate undertaking of requisite public health measures for the same.

4. In this context, all states are requested to ensure that as far as possible samples of all positive cases, on a daily basis, are sent to the designated INSACOG Genome Sequencing Laboratories (IGSLs) that are mapped to the States and UTs.

5. Ministry of Health & Family Welfare commends the consistent hard work put in by all States/UTs and will continue to extend required support to all states in this regard.

Yours sincerely

(Rajesh Bhushan)

Addl. Chief Secretary/Principal Secretary/Secretary (Health) of all States/UTs

Copy for information to:
- Secretary, DBT
- Secretary (DHR) & DG, ICMR
- DGHS/Director, NCDC

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**First Nasal Vaccine against COVID-19 supported by DBT-BIRAC gets emergency use authorization from DCGI**

Central Drugs Standard Control Organization (CDSCO) has granted approval for Bharat Biotech’s BBV154 vaccine for treating Covid-19. BBV154 is claimed to be the first intranasal vaccine for Covid-19 in the world. It has been approved for restricted use in emergencies for people aged 18 and above in India for the first two-dose schedule and homologous booster doses.

The Department of Biotechnology (DBT) and its PSU, Biotechnology Industry Research Assistance (BIRAC), supported Bharat Biotech in developing the new intranasal vaccine for Covid-19. Under the Mission COVID Suraksha Program, DBT, the Indian Government and BIRAC provided funding for the development and clinical trials of the vaccine. Phase III trials of BBV154 were conducted to evaluate its safety and immunogenicity in approximately 3100 participants in 14 trial sites across the country.

The vaccine was also assessed in heterologous booster dose studies to study the safety and immunogenicity in nearly 875 participants. In the studies, a booster dose of the intranasal BBV154 vaccine was given to the participants who had received licensed Covid-19 vaccines earlier. Now it is available at co-win portal.

Ref. Pharmaceutical Technology

**Benzodiazepines Potential risk of abuse, dependence and withdrawal**

The Medsafe has reminded prescribers of the recent update to the product information for benzodiazepines regarding the potential risks of abuse, dependence and withdrawal, even when taken at recommended dosages. New Zealand dispensing data shows that diazepam and lorazepam are the most dispensed benzodiazepines. The total amount of these medicines that were dispensed for all indications has increased in the period between 2016 and 2020 which may suggest frequent and/or long-term use. Between August 1969 and March 2022, the CARM received 23 case reports of withdrawal and/or dependence with the use of benzodiazepines. Clonazepam (nine cases) was the most frequently reported benzodiazepine, followed by lorazepam (five), diazepam (three) and triazolam (three). Health-care professionals are advised to counsel patients about the risks of benzodiazepines when initiating treatment, regularly review the ongoing need for treatment, and gradually taper benzodiazepines following continuous or high-dose use to reduce the risk of withdrawal reactions.

Reference: Prescriber Update, Medsafe, June 2022 (link to the source within www.medsafe.govt.nz/)

**Pembrolizumab Potential risk of cholestasis**

The SFDA has identified a safety signal for pembrolizumab (Keytruda®) and the potential risk of cholestasis. In 2021, the SFDA detected the signal by reviewing the medical literature. The SFDA extracted and reviewed ICSRS that were most complete (completeness score of >0.8) from the local and WHO global databases. WHO causality assessment criteria were applied on the extracted cases and most of cases were assessed to have a positive association (out of 33 ICSRs: one case was assessed to be certain, 10 probable, and seven possible cases). The investigation concluded that the current available evidence is sufficient to support the relationship between pembrolizumab and cholestasis. This signal needs further investigation to
confirm the risk, and health-care professionals should be aware of this potential adverse reaction.
Reference: Safety Alert, SFDA, 28 March 2022 (link to the source within www.sfda.gov.sa) Secukinumab

Pregabalin Risk of major congenital malformations in children exposed in-utero
The MHRA has announced that the product information for pregabalin will be updated to include information from a new study which has suggested pregabalin may slightly increase the risk of major congenital malformations if used in pregnancy. Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults, as adjunctive therapy in adults with partial seizures with or without secondary generalization, and for generalized anxiety disorder in adults.

The MHRA reviewed the results of a Nordic observational study that consisted of 2,700 pregnancies exposed to pregabalin in the first trimester, alongside a recent European review which had the same conclusions. The study showed a higher prevalence of major congenital malformations in the babies (live or stillborn) exposed to pregabalin in the first trimester of pregnancy compared with those not exposed to pregabalin or any other antiepileptic drug. The review concluded that pregabalin use during the first trimester of pregnancy may cause a slight increase in risk of major congenital malformations in the unborn child. The product information continues to advise that effective contraception should be used during treatment and that use in pregnancy should be avoided unless it is clearly necessary.
Reference: Drug Safety Update, MHRA, 19 April 2022 (link to the source within www.gov.uk/mhra)

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