ADVISORY

USE OF REMDESIVIR IN THE CURRENT COVID-19 PANDEMIC.

Date: 19th of June, 2020.

Target Audience:

- Drugs Inspectors (Federal and Provincial);
- Public and Private Hospitals;
- Pharmaceutical Companies and Distributors of Remdesivir;
- Healthcare Professionals;
- Patient/ Consumer of the drug.

Background.

There are no drugs or other therapeutics presently approved in the world that is used to prevent or treat COVID-19. Current clinical management includes infection prevention and control measures and supportive care, including supplemental oxygen and mechanical ventilatory support when indicated. However, across the world different healthcare professionals and investigators are using different investigational drugs in COVID-19 to determine their effectiveness in these patients. Some of these drugs also got emergency use authorization across the world for the treatment of COVID-19 patients. One of such investigational antiviral drug is Remdesivir that has the potential in management of COVID-19 disease. The United States Food and Drug Administration on 1st May, 2020 issued an emergency use authorization for the investigational antiviral drug remdesivir for the treatment of suspected or laboratory-confirmed COVID-19 in adults and children hospitalized with severe disease as the drug has shown in a clinical trial to shorten the time to recovery in some patients. Severe disease is defined as patients with low blood oxygen levels or needing oxygen therapy or more intensive breathing support such as a mechanical ventilator.

Emergency Use Authorization of Remdesivir in Pakistan:-

It is in the mission of Drug Regulatory Authority of Pakistan to provide earliest availability of new treatment opportunities for the people of Pakistan. Based on this mission, DRAP in its 84th meeting held on 1st June, 2020, discussed the priority registration/ emergency use authorization of remdesivir for use in COVID-19 and decided for registration of remdesivir in light of emergency use authorization granted by Reference Regulatory Authorities. Subsequently, Registration Board in its 295th meeting held on 8th to 11th June, 2020 decided to grant emergency use authorization under Rule 29 (6) (8) of Drugs (Licensing, Registering and Advertising) Rules, 1976 with same precautions/ terms and conditions as adopted by Reference Regulatory Authorities.

Therapeutic Good:-

Remdesivir is a direct acting antiviral drug that inhibits viral RNA synthesis. It is an investigational drug and is not currently approved for any indication. Remdesivir has activity in cell culture and animal models against SARS-CoV, MERS-CoV, and SARS-CoV-2. Based on review of the topline data from the randomized, double-blinded, placebo-controlled trial conducted by NIAID (NCT04280705) and from the Gilead-sponsored open-label trial that evaluated different durations of remdesivir (NCT04292899), it is reasonable to believe that the known and potential benefits of remdesivir outweigh the known and potential risks of the drug for the treatment of patients hospitalized with severe COVID-19.

DRAP, Islamabad | 92 51 910 7413 | npc@dra.gov.pk

Advisory on the use of Remdesivir:-

i. In order to avoid the hoarding, profiteering and the distribution of remdesivir through black market, and its irrational use by healthcare professionals through private clinics, the Drug Regulatory Authority of Pakistan has decided that the use of remdesivir should be restricted to hospitals and health facilities of COVID-19. In this regard, DRAP advised pharmaceutical companies, authorized distributors of remdesivir in Pakistan to provide remdesivir to those public and private hospitals where treatment of COVID-19 patient is going on;

ii. Pharmaceutical companies and distributors shall through process of inventory control maintain record regarding distribution/ dispensing of the authorized remdesivir (i.e., lot numbers, quantity, receiving site, receipt date);

iii. Similarly, hospitals and health facilities shall through a process of inventory control maintain records regarding the dispensed authorized remdesivir (i.e., lot numbers, quantity, receiving site, receipt date), product storage, and maintain patient information (e.g., patient name, age, disease manifestation, number of doses administered per patient, other drugs administered);

iv. Use of remdesivir outside the public and private hospitals of COVID-19 should be reported to Quality Assurance and Lab testing Division of DRAP and respective Chief Drug Inspector of the Province;

v. Drug Inspectors, both Federal and Provincial are advised to ensure the use of remdesivir in public and private hospitals of COVID-19 only;

vi. Remdesivir should be used only to treat adults and children with suspected or laboratory confirmed COVID-19 and severe disease defined as SpO2 ≤ 94% on room air, requiring supplemental oxygen, mechanical ventilation, or extracorporeal membrane oxygenation (ECMO);

vii. Remdesivir should be administered in an in-patient hospital setting via intravenous (IV) infusion by a healthcare provider under strict supervision of qualified specialist/ physician;and

viii. Possible side effects of remdesivir include: increased levels of liver enzymes, which may be a sign of inflammation or damage to cells in the liver; and infusion-related reactions, which may include low blood pressure, nausea, vomiting, sweating, and shivering. Hospitals, Healthcare professionals and patients are requested to report any suspected adverse drug reactions to Pakistan National Pharmacovigilance Centre, Drug Regulatory Authority of Pakistan through DRAP Med Vigilance e-reporting system http//: https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PK or at npc@dra.gov.pk.