

COVID-19 Updates

Status of Remdesivir

Posted On: 14 JUN 2020 3:39PM by PIB Delhi

There are reports in a section of the media regarding the use of Remdesivir as part of the Clinical Management Protocol for COVID-19, and its availability in the country.

An updated Clinical Management Protocol for COVID-19 has been released by the Ministry of Health and Family Welfare on 13th June, 2020 in which the drug Remdesivir has been included as an “investigational therapy” only for restricted emergency use purposes along with off label use of Tocilizumab and Convalescent Plasma. The said protocol also clearly mentions that the use of these therapies is based on limited available evidence and limited availability at present. Use of Remdesivir under emergency use may be considered in patients with moderate disease (those on oxygen) but with no specified contraindications.

This drug has still not been approved (market authorization) by the US Food and Drug Administration (USFDA), where like India it continues only under an Emergency Use Authorization.

Restricted Emergency Use of drugs in the country for treatment of suspected or laboratory confirmed COVID-19 in adults and children hospitalised with severe disease is subject to the following conditions- Written informed consent of each patient required, results of additional clinical trials to be submitted, active surveillance data of all treated patients to be submitted, risk management plan along with active post marketing surveillance and reporting of serious adverse events also to be submitted. Additionally, first three batches of imported consignments are to be tested and reports submitted to Central Drug Standard Control Organisation (CDSCO).

M/s Gilead had applied to the Indian Drug Regulatory Agency, namely CDSCO, for import and marketing of Remdesivir on 29th May, 2020. After due deliberations, permission under Emergency Use Authorization was granted on 1st June, 2020 in the interest of patient safety and obtaining further data.

Six Indian companies, namely M/s Hetero, M/s Cipla, M/s BDR, M/s Jubilant, M/s Mylan and Dr. Reddy's Labs have also applied to CDSCO for permission to manufacture and market the drug in India. Five of these have also entered into an agreement with M/s Gilead. These applications are being processed by the CDSCO on priority and in accordance with the laid down procedures. The companies are at various intermediate stages of inspection of manufacturing

facilities, verification of data, stability testing, emergency laboratory testing as per protocol etc. Being an injectable formulation, testing for assay, identity, impurities, bacterial endotoxin test and sterility become very critical for patient safety and this data need to be provided by the companies. CDSCO is awaiting the data and is providing complete support to these companies. It has already waived off the requirement of local clinical trials for these companies by invoking emergency provisions. The regulatory processes are being facilitated and expedited by CDSCO.

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(Release ID: 1631509)