

## **NOTICE**

**Dated:02-07-2020**

### **Approval of Favipiravir Tablets to Glenmark Pharmaceuticals and Remdesivir Injection to Cipla Ltd, Hetero Drugs and Mylan Labs**

Considering the emergency and unmet medical need for Covid-19 disease, CDSCO has approved Restricted Emergency Use of Remdesivir Injectable Formulations for treatment of patients with severe COVID-19 infection and Favipiravir Tablets for mild to moderate COVID-19 infection subject to various conditions and restrictions.

Initially, Remdesivir formulation of the innovator was approved on 01.06.20 for import and marketing the drug in the country. However, the importer is yet to import the drug after taking import licence from CDSCO.

Further, on 20.06.2020 and 02/07/2020, CDSCO has granted permission to manufacture and market the same injectable formulations of the drug to the indigenous manufacturers for the same indication, restriction and conditions for use as stipulated for innovator's product. This will ensure early access of Remdesivir for treatment of severe COVID patients in the country under the Restricted Emergency Use.

Favipiravir Tablet has been approved for manufacture and marketing on 19.6.2020.

Both Remdesivir and Favipiravir formulations are required to be sold under the prescription of medical specialists only. Further, Remdesivir formulations are required to be supplied for use only to the hospital / institutions to ensure proper use of the drug as recommended. In both the cases, informed consent of the patient or his /her representative in the prescribed form is mandatory before initiating the treatment.

**DCGI**