

## Many steps taken to ensure smooth supply of Essential Drugs: Govt

By TIOL News Service

**NEW DELHI, AUG 04, 2021:** THE Government took various measures to increase the supply of essential drugs such as granting expeditious approvals to new manufacturing sites of existing manufacturers to enhance their production capacity, issuing licenses to new manufacturers/importers, helping the manufacturers in sourcing raw material and helping importers of drugs in getting maximum supplies on priority from the importing countries through support from diplomatic channels, restricting exports for a certain period, and allocating the drugs namely Remdesivir, Tocilizumab and Amphotericin B, during the period of limited supply, to States in an equitable manner to ensure availability of these drugs across the country. Domestic production and import of critical drugs was monitored regularly by the Government. Regular meetings were held with manufacturers to identify and address the issues faced by the manufacturers in the augmentation of the production. The availability of all major drugs required for management of COVID-19 was regularly monitored through weekly surveys of retail pharmacies.

Remdesivir is a patented drug of Gilead Life Sciences USA, manufactured in India under voluntary licenses granted by the patent holder to 7 Indian pharmaceutical companies. With the accelerated approval of 40 additional manufacturing sites by the Central Drugs Standard Control Organisation ( CDSCO ), the number of approved manufacturing sites has increased from 22 in mid-April, 2021 to 62 in June, 2021. The domestic production capacity of all the seven licensed manufacturers was thus augmented from 38 lakh vials per month in mid-April, 2021 to nearly 122 lakh vials per month in June, 2021. Total domestic production of Remdesivir by seven licensed manufacturers between 1 st April and 25 th July, 2021 is 1,68,14,752 vials.

Tocilizumab is a patented drug of Hoffman La Roche, a Swiss multinational company. It is not manufactured in India and is available in India through imports only. Its imported quantity was maximized through persistent efforts of the Government with the sole manufacturer of Tocilizumab. 1,00,020 vials (80 mg) and 13,001 vials (400mg) were commercially imported between 1 st April and 25th July, 2021. In addition, 50,024 vials (80 mg) were received in donation from Roche in the month of May, 2021.

Department of Pharmaceuticals and the Drug Controller General of India (DCGI) actively coordinated with the industry for identification of manufacturers and expeditious approvals of new manufacturing facilities. The DCGI issued manufacturing/marketing permission of Amphotericin B Liposomal Injection to 11 new companies in the months of May and June, 2021. The domestic production of Liposomal Amphotericin B between 1 st May and 30 th June, 2021 is 4,53,555 vials. The expected production in the month of July, 2021 is 3,45,864 vials.

Department of Pharmaceuticals and the Indian Embassy in the USA worked continuously with importers and manufacturers to maximise the quantity of imports of Liposomal Amphotericin B and also for early delivery of supplies. The total import of Liposomal Amphotericin B between 1 st May and 29 th July, 2021 is 10,77,677 vials. Indian Missions all over the world were instructed to immediately identify additional sources of the Liposomal Amphotericin B. MEA also helped domestic manufacturers in getting supplies of key excipients viz. HSPC and DSPG-Na required for production of Liposomal Amphotericin B from sources abroad. ^ ^ ^

The domestic production and imports of other drugs required for the management of COVID-19 namely dexamethasone, methylprednisolone, paracetamol etc. was monitored regularly and there was sufficient availability of these drugs to meet the increased demand.

The allocation of Remdesivir, Tocilizumab and Amphotericin B was started on 21 st April, 27 th April and 11 th May, 2021 respectively. The allocation of Remdesivir and Amphotericin B has now been discontinued due to sufficient availability of these medicines. The last allocation of Remdesivir was done on 23 rd May, 2021 and that of Amphotericin B was done on 24 th July, 2021. In addition to above commercial supplies, Central government has supplied to States free of cost Remdesivir, Tocilizumab and Amphotericin B received through Donation and also procured by the Central Government.

This information was given by the Minister of Health & Family Welfare and Chemicals & Fertilizers, Mr Mansukh Mandaviya in a written reply in Lok Sabha yesterday.