

**GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS**

RAJYA SABHA
STARRED QUESTION No. 51
TO BE ANSWERED ON THE 23rd July, 2021

Shortage of antiviral drugs

51 Dr. L. Hanumanthaiah:

Will the Minister of **Chemicals and Fertilizers** be pleased to state:

- (a) whether Government has taken cognizance of shortage of antiviral drugs such as Remdesivir and Tocilizumab;
- (b) if so, the details thereof and the actions taken to address this shortage;
- (c) whether Government, exercising its powers under the Patents Act, intends to issue compulsory licenses to generic pharmaceutical companies for manufacturing of low-cost versions of Remdesivir and Tocilizumab;
- (d) if so, the details thereof and if not, the reasons therefor; and
- (e) the number of Remdesivir manufacturers in the country and their production capacity, year-wise, from 2019 till date?

ANSWER

**MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI MANSUKH MANDAVIYA)**

(a) to (e): A statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO PARTS (a) TO (e) OF STARRED QUESTION NO. 51 FOR REPLY ON 23.07.2021

(a) to (b): Yes, Sir. Shortages were noticed in the months of April and May in case of Remdesivir and Tocilizumab due to the sudden surge in demand of these drugs for managing COVID-19 patients. It may be noted that both these drugs are patented drugs. Remdesivir is manufactured in India whereas Tocilizumab is available in India through imports only. To address the shortages, government immediately started working on augmenting supply of these drugs by augmenting domestic production in case of Remdesivir and by making efforts for increased quantity of imports in case of Tocilizumab. Due to collective efforts made in this direction by seven domestic manufacturers of Remdesivir and with the grant of expeditious approvals by Drug Controller General of India, the number of licensed manufacturing sites of Remdesivir in India increased from 22 in mid-April to 62 at present. The domestic production capacity of Remdesivir increased from 38 lakh vials per month in mid-April to 122 lakh vials per month now. Similarly, in case of Tocilizumab, the imported quantity was maximised due to persistent efforts of the government with the sole manufacturer of Tocilizumab.

Further, in order to secure domestic supply of Remdesivir, the export of Remdesivir Injection and Remdesivir API (Active Pharmaceutical Ingredient) was prohibited from 11th April, 2021. In addition, Department of Pharmaceuticals (DoP) and Ministry of Health and Family Welfare (MoH&FW) jointly undertook an exercise for allocation of available stocks of Remdesivir and Tocilizumab to all the States/UTs of the country in a move to mitigate shortage and to ensure fair and equitable distribution across the country. The total allocation and supply of these two drugs is given as under:

Sr. No.	Name of the drug	Allocation to States/UTs and Central Institutions (in vials)	Supply to 18.07.2021 till (in vials)
1.	Remdesivir Injection	98,87,000	97,03,393
2.	Tocilizumab (400 mg) Injection	9,900	9,578
3.	Tocilizumab (80 mg) Injection	65,000	53,284

In addition to the above allocation of commercial supplies to States/UTs, the MoHFW has also distributed the following, free of cost, to the States/UTs:

- 21,86,936 vials of Remdesivir purchased from the domestic manufacturers.
- 8,23,862 vials of Remdesivir sourced from outside India through donation and commercial purchases.
- 1,001 vials of Tocilizumab (400 mg) received in donation from Oman have been distributed to States/UTs.
- 27,381 vials of Tocilizumab (80 mg) received in donation from Roche have been distributed to States/UTs.

As on today, the demand of Remdesivir has come down considerably and the demand supply gap has reversed in the sense that supply is much more than the demand. Accordingly, Remdesivir has been moved from Prohibited to Restricted Category of Exports on 14th June, 2021. Similarly, the demand-supply position for Tocilizumab has stabilized considerably and some States are not placing purchase orders with the company marketing Tocilizumab as per

quantities allocated by Central government to them. The states and UTs have been advised to procure buffer stocks to deal with any future requirements.

(c) & (d): No sir. There is no application filed for invoking compulsory licensing under Section 84 of the Patents Act with central Government by manufacturer or party intending to manufacture Remdesivir or Tocilizumab. Further, the manufacturing capacity of Remdesivir, a patented drug has been ramped up from 38 lakh vials per month to 1.22 crore vials per month now, by the seven domestic manufacturers that have been licensed in 2020 by Gilead Sciences Inc, a USA based multinational company, holding the patent for Remdesivir. Tocilizumab is also a patented drug of Hoffman La Roche, a Switzerland based multinational company and is not manufactured in India. It is pertinent to note that the Central Drugs Standard Control Organisation (CDSCO) under MoHFW, has on 12th May, 2021 given permission to one Indian pharmaceutical company for conducting phase three clinical trials for a bio-similar drug.

(e): As per CDSCO, Remdesivir injection was approved on 20.06.2020 in the country. Presently, 62 manufacturing sites of 7 manufacturers are approved for manufacturing Remdesivir injection with total monthly installed capacity of 122 lakh vials/month.

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