GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION NO. 348
TO BE ANSWERED ON 15th September, 2020

Availability of Remdesivir

348. SHRI PRATHAP SIMHA:
SHRI L.S. TEJASVI SURYA:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) the details of the current availability of Remdesivir with different pharmaceuticals companies and the demand for anti viral from different States;
(b) whether production of remdesivir by Pharma companies in India is able to match the requirement, if so, the details thereof, and if not, the estimated shortage;
(c) the names of the companies with the license to manufacture Remdesivir in the country;
(d) whether the Government has received more applications requesting for license to manufacture remdesivir, if so, the details and states thereof;
(e) whether the Government is permitting pharma companies to import remdesivir from foreign countries who are in advanced stages of production and if so, the details thereof; and
(f) the measures taken by the Government to bring the price of Remdesivir under control in the country?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI D. V. SADANANDA GOWDA)

(a) & (b): The details of total quantity of Remdesivir injection manufactured so far by the pharmaceutical companies are as follows:

Sl. No.	Name of the Pharmaceutical company	Total quantity of Remdesivir manufactured for market till 08-09-2020
1.	M/s Mylan Laboratories limited	500,000 vials
2.	M/s Hetero Healthcare	14,46,000 Vials
3.	M/s Jubilant Generics Limited	150,000 vials
4.	M/s Cipla*(as on 28-08-2020)	143,329 vials
5.	M/s Dr. Reddy's Laboratories	13286 units
6.	M/s Cadila Healthcare Limited	1,86,957 vials

The Central Drugs Standard Control Organisation (CDSCO) has not received any report that Pharma companies are not being able to match the current demand.

(c) to (e): Initially, CDSCO has granted permission to M/s Klinera to import and market Remdesivir injection 100 mg/20 ml and Remdesivir 100mg/vial lyophilised powder of M/s Gilead for Restricted Emergency Use in the country for treatment of suspected or laboratory confirmed corona virus disease 2019 (COVID-19) in adults and children hospitalised with severe disease subject to various conditions / restrictions.

Based on the above import and marketing permission, M/s Klinera has submitted application for import registration certificate and import license to CDSCO for which firm needs to submit additional documents.

Subsequently, CDSCO has granted permission to manufacture and market Remdesivir Injectable Formulations for restricted emergency use in the country, subject to various conditions and restrictions to the following manufacturers:

S. No	Firm Name	Permission Date
1	M/s. Hetero	20/06/2020
2	M/s. Cipla	20/06/2020
3	M/s Mylan	02/07/2020
4	M/s Jubilant	22/07/2020
5	M/s Cadila Healthcare Ltd	06/08/2020
6	M/s Dr. Reddy's	10/08/2020

Further, CDSCO had received applications from M/s MSN Labs and M/s BDR Pharmaceutical limited for which applicant need to submit additional documents.

(f): The National Pharmaceutical Pricing Authority (NPPA) fixes/revises the ceiling price of Scheduled medicines specified in First Schedule of the Drugs (Prices Control) Order, 2013 (DPCO, 2013). The NPPA also monitors the prices of non-scheduled medicines so that their MRP does not increase by more than 10 percent of the MRP during preceding twelve (12) months.

Further, Remdesivir is included under 'Investigational Therapy category' and is being used as off-Label and Emergency Use Authorization (EUA) drug. The Drugs Controller General of India (DCGI) has given conditional license to this formulation for "restricted emergency use". These medicines are being administered after obtaining consent of the patient. Hence, full drug status has not been granted to these drugs for COVID-19 treatment. As noted above, presently, there are six manufacturers of Remdesivir Injection and its pricing is being governed by market dynamics.

Initially, the manufacturers of Remdesivir Injection namely M/s Mylan Laboratories, M/s Hetero Healthcare Limited and M/s Cipla Limited were advised by Central Drugs Standard Control Organization (CDSCO) to upload information regarding distributors and supply chain details along with the quantities on their website, so as to prevent black-marketing and overcharging of the drug.

On receipt of complaints regarding selling of Remdesivir at a price above MRP, necessary instructions were issued to the Drugs Controller General of India (DCGI) to advise the manufacturers to start a 24x7 helpline for patients and their families in case the medicine is not available or higher price is being charged. In compliance, manufacturers started helpline number and displayed it on website. Further, contact details of manufacturers were provided on the website of the NPPA i.e. www.nppaindia.nic.in, to facilitate information regarding availability of medicine for the public.

The NPPA also set-up a Control Room with Helpline No. 1800111255 and e-mail monitoring-nppa@gov.in on 20th March 2020 to respond to queries and complaints relating to COVID-19. The issues raised are addressed and resolved; solutions are provided and forwarded to concerned authorities for redressal and followed up for final resolution.

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