GOVERNMENT OF INDIA MINISTRY OF CHEMICALS & FERTILIZERS DEPARTMENT OF PHARMACEUTICALS

LOK SABHA UNSTARRED QUESTION NO. 2440 TO BE ANSWERED ON 03rd August, 2021

Supply of Essential Drugs

2440. SHRI PRATHAP SIMHA: SHRI L.S. TEJASVI SURYA:

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

- (a) the details of the measures taken by the Government in increasing the supply of essential drugs during the second wave of the COVID-19 pandemic in the country;
- (b) the details of the incremental supply and production of remdesivir, tocilizumab, liposomal amphotericin B and other drugs that were used in the treatment of COVID-19 infections in the country; and
- (c) the statewise supply information of the above drugs used in the treatment of COVID-19 during each increment/phase?

ANSWER

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

(a): 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.

(b) & (c):

(i) 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 1st April and 25th July, 2021 is 1,68,14,752 vials.

- (ii) 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 1st April and 25th July, 2021. In addition, 50,024 vials (80 mg) were received in donation from Roche in the month of May, 2021.
- (iii) 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 1st May and 30th 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 1st May and 29th 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.

(iv) 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 21st April, 27th April and 11th 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 23rd May, 2021 and that of Amphotericin B was done on 24th July, 2021. The State-wise supply of Remdesivir, Tocilizumab and Amphotericin B by pharmaceutical companies in pursuance to allocation given by the Central government and purchase orders placed by States/ UTs is given in a Table in Annexure 1. 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. The State-wise data of Remdesivir, Tocilizumab and Amphotericin B supplied by the Central government free of cost is given in a Table in Annexure 2.

No. of vials of Remdesivir, Tocilizumab, Amphotericin B supplied to States and Union Territories (UT) by pharmaceutical companies against allocation given by the Central Government (Supply status as on 25^{th} July, 2021)

S.N.	State/UT	Remdesivir	Tocilizumab	Amphotericin B
1	Andaman and Nicobar Islands	3300	30	0
2	Andhra Pradesh	780152	2321	105315
3	Arunachal Pradesh	4946	0	0
4	Assam	117505	550	350
5	Bihar	162800	1415	12600
6	Chandigarh	25496	155	4960
7	Chhattisgarh	228366	430	6410
8	Dadra and Nagar Haveli & Daman Diu	3368	80	51347
9	Delhi	284809	1516	500
10	Goa	43550	400	1200
11	Gujarat	856288	2070	222282
12	Haryana	298469	1575	47758
13	Himachal Pradesh	42202	150	220
14	Jammu and Kashmir	74947	870	3270
15	Jharkhand	182187	770	3780
16	Karnataka	983844	9743	80684
17	Kerala	198113	8660	14180
18	Ladakh	1500	30	0
19	Lakshadweep	500	0	0
20	Madhya Pradesh	359525	1465	65611
21	Maharashtra	1873758	11253	198300
22	Manipur	22586	130	150
23	Meghalaya	18190	65	0
24	Mizoram	5618	30	0
25	Nagaland	834	30	0
26	Odisha	176251	1752	2660
27	Puducherry	23252	25	730
28	Punjab	195717	1403	21970
29	Rajasthan	363395	2875	124156
30	Sikkim	3930	0	0
31	Tamil Nadu	1123905	4637	83210
32	Telangana	466590	1113	75705
33	Tripura	5250	30	100
34	Uttar Pradesh	534914	625	75398
35	Uttarakhand	102370	2000	5830
36	West Bengal	237499	2247	3585
	Total	98,05,926	6,0445	12,12,261

No. of vials of Remdesivir, Tocilizumab, Amphotericin B supplied free of cost by the Central Government to States and Union Territories (UT) (Supply status as on 25^{th} July, 2021)

S.No.	State/UT	Remdesivir	Tocilizumab	Amphotericin B
1	Andaman and Nicobar Islands	3380	10	
2	Andhra Pradesh	246436	2357	1147
3	Arunachal Pradesh	9839	11	
4	Assam	89109	263	2
5	Bihar	23826	659	54
6	Chandigarh	7149	52	16
7	Chhattisgarh	45008	790	34
8	Dadra and Nagar Haveli & Daman Diu	2685	10	
9	Delhi	62250	528	308
10	Goa	17664	261	7
11	Gujarat	32253	917	1251
12	Haryana	19042	786	411
13	Himachal Pradesh	9383	262	5
14	Jammu and Kashmir	23893	266	11
15	Jharkhand	15515	392	39
16	Karnataka	327378	3676	965
17	Kerala	224922	2763	37
18	Ladakh	4807	10	
19	Lakshadweep	3822	10	
20	Madhya Pradesh	136430	657	584
21	Maharashtra	447188	3940	1290
22	Manipur	17267	26	1
23	Meghalaya	6269	21	
24	Mizoram	6193	10	
25	Nagaland	5138	16	
26	Odisha	155857	526	20
27	Puducherry	8810	89	51
28	Punjab	46565	526	123
29	Rajasthan	123692	1316	1011
30	Sikkim	3814	16	
31	Tamil Nadu	556851	929	1063
32	Telangana	62069	394	965
33	Tripura	4927	16	
34	Uttar Pradesh	147223	1442	642
35	Uttarakhand	15133	525	26
36	West Bengal	37446	789	91
`	Total	29,49,233	25,261	10,154
