31	STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2021-22) SEVENTEENTH LOK SABHA

MINISTRY OF CHEMICALS AND FERTILIZERS
(DEPARTMENT OF PHARMACEUTICALS)

AVAILABILITY OF MEDICINES AND MEDICAL DEVICES FOR COVID MANAGEMENT

THIRTY- FIRST REPORT

LOK SABHA SECRETARIAT

NEW DELHI

March, 2022/ Phalguna, 1943 (Saka)

CC&F.No. 159

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CHEMICALS AND FERTILIZERS

(2021-22)

(SEVENTEENTH LOK SABHA)

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(DEPARTMENT OF PHARMACEUTICALS)

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Presented to Lok Sabha on 21 March 2022

Laid in Rajya Sabha on 21 March 2022

LOK SABHA SECRETARIAT

NEW DELHI

March, 2022/ Phalguna, 1943 (Saka)

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COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS

(2020-21)

Smt. Kanimozhi Karunanidhi - Chairperson

MEMBERS

LOK SABHA

2 Shri Maulana Badruddin Ajmal
3 Shri Deepak Baij
4 Shri Ramakant Bhargava
5 Shri Prataprao Govindrao Patil Chikhalikar
6 Shri Rajeshbhai Naranbhai Chudasama,
7 Shri Ramesh Chandappa Jigajinagi
8 Shri Pakauri Lal
9 Shri Kripanath Mallah
10 Shri Satyadev Pachauri
11 Smt Aparupa Poddar
12 Dr. M.K.Vishnu Prasad
13 Shri Atul Kumar Singh alias Atul Rai
14 Shri Arun Kumar Sagar
15 Shri M. Selvaraj
16 Shri Pradeep Kumar Singh
17 Shri Uday Pratap Singh
18 Shri Indra Hang Subba
19 Shri Er. Bishweswar Tudu
20 Shri Prabhubhai Nagarbhai Vasava
21 Dr. Sanjeev Kumar Singari

RAJYA SABHA

22 Shri G.C.Chandrashekhar
23 Dr. Anil Jain
24 Shri Ahmad Ashfaque Karim
25 Shri M.V. Shreyams Kumar
26 Shri Jaiprakash Nishad
27 Shri Anthiyur P. Selvarasu
28 Shri Arun Singh
29 Shri A.D. Singh
30 Shri Vijay Pal Singh Tomar
31 Shri K. Vanlalvena

SECRETARIAT

1. Shri Manoj K. Arora - Officer on Special Duty
2. Shri N.K. Jha - Director
3. Shri C. Kalyanasundaram - Additional Director
4. Ms. Sonia Sankhla - Assistant Committee Officer

COMPOSITION OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS (2021-22)

Smt. Kanimozhi Karunanidhi - Chairperson

MEMBERS

LOK SABHA

2. Shri Dibyendu Adhikari
3. Maulana Badruddin Ajmal
4. Shri Deepak Baij
5. Shri Ramakant Bhargava
6. Shri Prataprao Patil Chikhlikar
7. Shri Rajeshbhai Naranbhai Chudasama
8. Shri Sanjay Shamrao Dhotre
9. Shri Ramesh Chandappa Jigajinagi
10. Shri Kripanath Mallah
11. Shri Vasava Parbhubhai Nagarbhai
12. Shri Satyadev Pachauri
13. Smt Aparupa Poddar (Afrin Ali)
14. Dr. M.K.Vishnu Prasad
15. Shri Arun Kumar Sagar
16. Shri M. Selvaraj
17. Dr. Sanjeev Kumar Singari
18. Shri Atul Kumar Singh
19. Shri Pradeep Kumar Singh
20. Shri Uday Pratap Singh
21. Shri Indra Hang Subba

RAJYA SABHA

22. Shri Ayodhya Rami Reddy Alla
23. Shri G.C.Chandrashekhar
24. Dr. Anil Jain
25. Shri M.V. Shreyams Kumar
26. Shri Jaiprakash Nishad
27. Shri Anthiyur P. Selvarasu
28. Shri Arun Singh
29. Shri Vijay Pal Singh Tomar
30. Shri K. Vanlalvena
31. Vacant

SECRETARIAT

1.	Shri Vinod Kumar Tripahti	-	Joint Secretary
2.	Shri N.K. Jha	-	Director
3.	Shri C. Kalyanasundaram	-	Additional Director
4.	Ms. Sonia Sankhla	-	Executive Officer

INTRODUCTION

I, the Chairperson, Standing Committee on Chemicals and Fertilizers (2021-22) having been authorised by the Committee to submit the Report on their behalf, present this Thirty First Report (Seventeenth Lok Sabha) on 'Availability of Medicines and Medical Devices for COVID Management' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

2. The subject 'Availability of Medicines and Medical Devices for COVID Management' was taken up by the Standing Committee on Chemicals and Fertilizers (2020-21) and continued in Committee term (2021-22) for examination and report. The Committee took the oral evidence of the representatives of the Department of Pharmaceuticals on the subject at their sitting held on 29th June 2021.

3. The Standing Committee on Chemicals and Fertilizers (2021-22) considered and adopted this Report at their sitting held on 16th March 2022.

4. The Committee wish to express their thanks to the Officers of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) and Ministry of Health and Family Welfare for their cooperation in furnishing written information and for placing their views before the Committee.

5. The Committee also place on record their appreciation for the valuable assistance rendered to them by the officials of the Lok Sabha Secretariat attached to the Committee.

6. For facility of reference and convenience, the observations/ recommendations of the Committee have been printed in bold letters at the end of the Report.

New Delhi;
16 March, 2022
25 Phalguna, 1943 (Saka)

KANIMOZHI KARUNANIDHI
Chairperson,
Standing Committee on
Chemicals and Fertilizers.

REPORT

CHAPTER – I

INTRODUCTORY

A. Introduction

1.1 Corona Virus Disease 2019 (COVID-19) is an infectious disease caused by a newly discovered Corona virus named as 'Severe Acute Respiratory Syndrome Corona virus 2 (SARS-CoV-2)'. Since the initial emergence of COVID-19 in China, the disease has rapidly spread to other countries worldwide as a global threat. WHO declared the COVID19 outbreak a pandemic on 11 March 2020. COVID-19 pandemic is amongst the largest public health crisis faced by the World that is having unprecedented negative consequences on health, economy and our social lives. India is also affected by the COVID 19 pandemic. Since March, 2020, two waves of pandemic struck the country. First wave hit the country during the period March to October, 2020 and the second wave during the period March to June 2021. After the first wave, by the end of March, 2021, the COVID situation with respect to demand of essential medical services and drugs in the country appeared to have settled down. However, the sudden and drastic surge in the COVID cases in the country in April, 2021 during the second wave had led to sharp increase in the requirement for essential medical services including availability of drugs and associated medical devices. Since the fool proof measures are necessary to ensure the availability of medicines and medical devices to the people of all the regions of the country in the period of COVID-19 pandemic, the Committee decided to select and examine the subject "Availability of medicines and medical devices for COVID management" on priority basis.

B. Role of Department of Pharmaceuticals

1.2 The Department of Pharmaceuticals has the mandate of industry promotion for pharmaceutical industry and supports the Ministry of Health and Family Welfare in achieving the objective of affordable, universal, quality healthcare services. The listing of drugs for the COVID management and including the same in the National Treatment Protocol is done by Ministry of Health and Family Welfare (**MoHFW**). However, there are drugs which even though not in the National Treatment Protocol are prescribed by the physicians across the country and are in high demand. Accordingly, based on the inputs received from MoHFW from time to time, the Department of Pharmaceuticals has been working to augment the production and supply of the essential drugs required for management of COVID.

1.3 The Department of Pharmaceuticals undertook the task of making the essential COVID related drugs available across the country in active partnership with the manufacturers of these drugs. The monitoring of production and availability of drugs has been carried out as a joint exercise between Department of Pharmaceuticals (DoP), National Pharmaceuticals Pricing Authority (**NPPA**) under Department of Pharmaceuticals and the Central Drugs Standards Control Organisation (**CDSCO**) under the Ministry of Health and Family Welfare (MoH&FW). The CDSCO plays an important role in giving

approvals for manufacturing, marketing and distribution of the drugs and enforcement of drug licenses under the Drug and Cosmetics Act, 1940. The jurisdictions for the same are distributed between Drug Controller General of India (DCGI) in the Government of India and by State Drug Controllers (SDC) in the States/UTs.

1.4 On being asked, whether the Department of Pharmaceuticals has any role in framing of National Treatment Protocol prepared by the Ministry of Health and Family Welfare, the Department of Pharmaceuticals in their written reply stated as under:

> "The Department of Pharmaceuticals has no role to play in framing of National Treatment Protocol. The Department of Pharmaceuticals, if consulted can provide inputs mainly on production capacity and availability status of the drugs. However, this information is also available with CDSCO, which is under MoHFW."

1.5 The Committee asked about the details of the joint monitoring exercise between Department of Pharmaceuticals, NPPA under Department of Pharmaceuticals and the Central Drugs CDSCO under the Ministry of Health and Family Welfare (MoH&FW), the Department of Pharmaceuticals in their written reply stated as under:

> "The first step of the exercise included identification of the manufacturers of COVID drugs, which was done by CDSCO since all the existing manufacturers, new manufacturers, importers etc. require the approval for manufacturing, marketing, import etc. from the CDSCO. Further, the major existing manufacturers of COVID drugs are also identified by NPPA through a database of retail sales where the manufacturers having largest market share of COVID drugs were identified. Once the manufacturers were identified, their production and supply were monitored weekly by NPPA and CDSCO apart from some detailed monitoring on three specific drugs viz. Remdesivir, Tocilizumab and Amphotericin-B. NPPA interacted regularly with Nodal Offiecrs of States/ UTs and manufactures to coordinate supplies. The manufacturers were given all kind of support whether it was logistic issues, regulatory facilitation by CDSCO, assisting in imports of raw materials through Ministry of External Affairs and Indian Missions abroad, relief in taxation etc."

1.6 Further, when asked to state the major constraints that were noticed while undertaking the joint monitoring of production and availability of drugs, Department of Pharmaceuticals in a written reply stated as follows:-

> "There were two major constraints noticed in ensuring the availability of drugs in the initial few days of the surge of COVID cases. One is the lag time between manufacturing of the drug and its actual availability in the market. This time period is required with respect to the regulatory procedures which have a bearing on the safety and efficacy of the drug. This was however a necessary requirement. Second was import of certain raw materials for drugs, including the finished formulation like Tocilizumab which is not manufactured in India. MEA also provided assistance to all the manufacturers by coordinating with the overseas suppliers through Indian Missions abroad. **"**

1.7 In regard to the above, the Secretary, DoP further informed the Committee during briefing as under:-

"There are two constraints. One is time, because when you start manufacturing a drug like Remdesivir it takes two to four weeks before the drug can come out because it is a biological process or a bio-chemical process that time is required. That is one constraint. So, always whenever there is a surge in demand, in the initial days you see the tightness, but after that we are able to ramp up. The second constraint is in respect of certain raw materials. Even if we have the APIs in our country, domestically produced in India, there are a few raw materials in India called excipients where we are depending on foreign manufacturers. So, these are the two constraints. In our future planning we are trying to address these two constraints for which the Health Ministry is also working on a policy whereby we can build up a stock and ensure that there is availability even before the surge happens".

1.8 In regard to a query of the Committee about the strategy/action plan now the Department of Pharmaceuticals is chalking out to reduce the impact of these constraints on the availability and production of Covid medicines in case of another wave in the country, the Department of Pharmaceuticals in their post evidence reply stated as follows:

"The MoHFW has brought out a buffer policy vide which the States/UTs have been advised to maintain adequate buffer stocks of the drugs. The Central Govt is also maintaining a buffer stock of the drugs in case there is any eventuality in the form of third wave of COVID."

1.9 On being asked about the corrective measures or mid-course alternative measures that were taken to keep the situation under control so as to meet the drug needs of the country during pandemic, Department of Pharmaceuticals stated in their written reply stated as below:

"Two-pronged strategy was followed to augment the drug availability in the country. One is enhanced domestic manufacturing in India within a short span of time, which also included regulatory facilitation by CDSCO in terms of expeditious approvals to domestic manufacturers of COVID drugs. Secondly, imports of Tocilizumab and Amphotericin-B were also done to augment the availability."

C. Administrative Arrangements For Ensuring Availability of Medicines And Medical Devices

(a) Covid Drugs Management Cell (CDMC)

1.10 A COVID Drugs Management Cell (CDMC) has been set up in the Department of Pharmaceuticals (DoP) to oversee the management of smooth supply of drugs used in COVID-19 management during the pandemic. The CDMC was formally structured vide OM dated 26.4.2021 but the work under the same had started quite early in the first week of April 2021. Daily morning meetings of the CDMC are conducted to review and prioritize the actions required with respect to the issues surrounding drug production and availability. The CDMC has been able to respond to the COVID drug requirement of the country during the second wave with the collective support from the officials of Department of Pharmaceuticals, National Pharmaceuticals Pricing Authority (NPPA) and Central Drugs Standard Control Organization (CDSCO). Looking at the importance and the quantum of work, the DoPT also attached one Additional Secretary and five Directors with Department

of Pharmaceuticals who were then assigned specific tasks in the Department of Pharmaceuticals.

1.11 In view of above information furnished by the Department of Pharmaceuticals, when the Committee asked about the reasons for not setting up of COVID Drugs Management Cell (CDMC) in 2020 itself immediately after the onset of first wave of COVID-19 pandemic in the country and reasons for not envisaging the alarming situation which had arisen due to second wave, the Department of Pharmaceuticals in their written reply clarified as under:

> **"**The COVID Drugs Management Cell (CDMC) is a formalised coordination structure between Department of Pharmaceuticals and CDSCO under the MoHFW, so that daily progress can be monitored. The coordination between Department of Pharmaceuticals (DoP) and CDSCO has been happening since 2020 on various issues relating to drug availability, CDMC formalized this collaboration within Department of Pharmaceuticals (DoP) and CDSCO for drug availability and augmentation. In view of increased severity of the surge in April 2021, deputations of officers from other Departments to DoP/ NPPA in May-June, 2021 also facilitated setting up and smooth functioning of CDMC."

1.12 When the Committee further asked about the mechanism that is adopted by COVID Drugs Management Cell (CDMC) for equitable and fair distribution of medicines and medical devices required for COVID treatment as per the requirements of States/UTs, the Department of Pharmaceuticals furnished the following written reply:

> "The allocation of three drugs where acute shortages were initially noticed has been done to States/UTs and Central Govt. Hospitals, jointly by DoP and MoHFW. These are Remdesivir, Tocilizumab and Amphotericin-B. Allocation meant that the States/UTs and Central Govt. Hospitals had to place commercial purchase orders for the allocated quantity on the identified suppliers and procure the drugs. The allocation of drugs (Remdesivir, Tocilizumab and Liposomal Amphotericin B) was undertaken based on transparent and dynamic criteria, on a periodic basis in consultation of DoP and MoHFW, and feedback received from States."

1.13 On further being asked about details on task assigned to CDMC regarding assessment of drug/medicine requirements of the country in the wake of sudden onset of third wave of COVID pandemic, the Department of Pharmaceuticals in their written reply stated, **"**The COVID Drugs Management Cell (CDMC) takes inputs from MoHFW on estimation of drug requirements. The Department of Pharmaceuticals has the mandate of industry promotion and it coordinates with the pharmaceutical manufacturers/importers for augmentation of production and assisting them with all related issues."

(b) <u>Drugs Coordination Committee (DCC) and Empowered Group-2(EG-2)</u>

1.14 The Department of Pharmaceuticals also submitted in their background note that in order to formalise the inter-Departmental consultations on the issues with regard to drug availability, a Drugs Coordination Committee (DCC) was constituted vide OM 20.05.2021 as an institutional mechanism with representation from DoP, MoHFW, Directorate General of Health Services (DGHS), Indian Council of Medical Research (ICMR), Directorate

General of Foreign Trade (DGFT), Ministry of External Affairs (MEA), CDSCO and NPPA for efficient decision making on all the issues with respect to COVID-19 related drugs. Subsequently, vide MHA order dated 29.05.2021 for decisively and effectively addressing evolving changes from COVID-19, an Empowered Group-2 (EG-2) for Emergency Response Capabilities has been formed with Secretary D/o Health and Family Welfare as the convenor and Secretary, Department of Pharmaceuticals its member among other members. The subject “medicines” is tasked to the EG-2 besides Hospital beds with ICU and essential medical equipment for COVID. The work related to testing and diagnostic kits has been assigned vide the said MHA order to Empowered Group-6, convenor of which is Secretary DHR and DG ICMR.

1.15 In this regard, when the Committee asked about the reasons for late constitution of Drugs Coordination Committee (DCC) and also asked about the views of the Department of Pharmaceuticals on drugs and medical devices availability scenario in the country that would have been much better had the institutional mechanisms such as DCC and CDMC were put in place at the early stage of onset of the first wave of pandemic in the country, the Department of Pharmaceuticals furnished the following clarification in writing:

> "The DCC formalised the already existing coordination between Department of Pharmaceuticals and other Departments in a more structured manner. The setting up of the DCC facilitated the work done collectively by Department of Pharmaceuticals and other Departments on drug availability and augmentation. It may also be recalled that the challenges faced during the period April 2021 to June 2021 were far more complex and severe than the earlier phase of the pandemic in 2020."

1.16 Further the Department of Pharmaceuticals stated that till 01.9.2021, the Drugs Coordination Committee (DCC) has met seven times since its inception. Drugs Coordination Committee (DCC) deliberated on issues such as the need to build up a buffer stock of drugs, regulating exports of COVID drugs and coordinating with manufacturers for ramping up production so as to be in a state of preparedness for drug supply in the event of a future surge.

1.17 During the course of briefing held on 29.06.202, the Committee asked whether the Drug Coordination Committee is going to be a temporary one or a permanent one. In this regard, Department of Pharmaceuticals in their post evidence reply stated, "The DCC is an administrative arrangement for coordination till the time it is required. The DCC mechanism will be used as and when required."

1.18 Regarding composition of EG-2, Department of Pharmaceuticals in their written submission stated that the Ministry of Home Affairs (MHA) vide Order No.40-3/2020-DM-I(A) dated 29th May, 2021 has re-constituted Empowered Group-2 (EG-2) for Emergency Response Capabilities with Secretary, MoHFW as the Convener. The composition of the EG-2 is as under:

i. Shri Rajesh Bhushan, Secretary, Ministry of Health and Family Welfare - Convener
ii. Shri N.N. Sinha, Secretary, DoP of Rural Development- Member

iii. Ms. S. Aparna, Secretary, DoP- Member
iv. Shri B.B. Swain, Secretary, MSME- Member
v. Shri Krishna S Vatsa, Member, NDMA- Member
vi. ShriAlkesh Sharma, Addl. Secretary, Cabinet Secretariat- Member
vii. Shri S. Gopalakrishnan, Addl. Secretary, PMO- Member
viii. Shri Naveen Srivastava, Addl. Secretary, MEA- Member
ix. ShriSajjan Singh Yadav, Joint Secretary, DoP of Expenditure- Member
x. ShriMandeepBhandari, Joint Secretary, Health and Family Welfare- Member
xi. Dr. P. Ravindran, EMR, MoHFW- Member
xii. ShriSaurabhShukla, Director, PMO- Member

1.19 On being asked to furnish the details of meetings held by the Empowered Group-2 and their outcome, Department of Pharmaceuticals in its written reply stated that EG-2 has held seven meetings since its formation, till 16th September 2021. The main outcomes of the meetings are as follows:

(i) As per the DGFT notification dated 14th June 2021, Remdesivir has been shifted from Prohibited status to restricted status for export.

(ii) EG-2 through MEA continuously sourced Liposomal Amphotericin B (LAmB) Injections through its missions abroad, 1,50,000 Injection vials of LAmB landed in India and were distributed through HLL.

(iii) Buffer Stock Management Guidelines for COVID-19 drugs has been prepared for guidance of the States/ UTs to build up buffer stocks of essential COVID drugs and to ensure their availability for addressing any future surge in COVID cases. The guidelines were communicated to States/ UTs vide MoHFW's DO Letter No X.11035/178/2021-DRS dated 13th July, 2021 (**Annexure-6**).

(iv) As decided in the Fourth and Fifth meeting of EG-2, the two member committee of the Joint Secretaries of M/o HFW and D/o Pharmaceuticals, has been constituted for making recommendations to DGFT to consider the applications for export of Remdesivir and Amphotericin B.

(v) As decided in the sixth meeting of EG-2, the two-member committee along with Dr. M.K. Aggarwal, Addl. Commissioner, Immunization Division, MoHFW may henceforth also consider the applications for export of Syringes and make its recommendations.

(vi) As decided in the seventh meeting of EG-2, it was considered that Department of Pharmaceuticals will allocate Tocilizumab to all States based on proportion criteria suggested under the buffer stock policy and stock already available with States to ensure adequate availability with all States/UTs.

(vii) Department of Pharmaceuticals shall keep close watch on the production, supply, availability and export of IVIG.

(viii) Day to day monitoring by MoHFW of production, supply and export of syringes to ensure its availability for vaccination/UIP and to coordinate with all indigenous manufacturers of syringes for ensuring further additional supplies of syringes there by reducing the deficiency of 17 crore syringes to zero.

(ix) To monitor, Dash board developed by the MoHFW, availability of buffer stocks with the States/UTs on real time basis.

D. Supply Constraints of Medicines and Medical Devices During Second Wave and Corrective Measures being taken thereon.

1.20 During the briefing on the subject by the representatives of Department of Pharmaceuticals held on 29.06.20, the Committee asked about the robust mechanism that is available to keep a track of day to day distribution, availability and actual utilization of critical COVID medicines and medical devices at village, block, district, state and centre level and also the distribution between the Government and private hospitals. Further, the Committee observed that that the information regarding availability of critical medicines like Remdesivir, Tocilizumab, Amphotericin-B at district level with District Magistrate was not shared to COVID patients' family during second wave of pandemic. In this regard the Committee asked about the steps that are being taken by the DoP in coordination with State/UT administration to disseminate information regarding availability of life saving COVID drugs at district level by the district authority in future. In regard to the above questions of the Committee, Department of Pharmaceuticals in their post evidence reply furnished the following information:

"The drugs allocated to the States/UTs and procured by them are kept at the disposal of the State Governments. Thereafter, the State/UT Governments are expected to monitor the actual utilisation of the drug at further administrative levels in their jurisdictions. Further, the Ministry of Health and Family Welfare is operating a COVID-19 portal in which all States can fill in and access real time information. COVID 19 INDIA PORTAL is a Real time web platform to analyze, understand and keep track on COVID pandemic situation across country. This portal is getting used by more than 20,000 users from various level such as National / State/ District / Facility. The following information is available on the portal www.covid19.nhp.gov.in-

- Details on case load and trajectory to help containment decisions.
- Details on drive testing volume, tests per day etc.
- Details on improving quality of care for COVID-19 patients.
- Details of different types of dedicated COVID facilities.
- The status of different types of ambulances available in the state.
- Details of Quarantine facilities at states level.
- Details of Testing equipment and Reagents available.
- Analysis of Mucormycosis cases.
- Analysis of all facilities available in the state
- Fatality Analysis.

From the data fed in by the states a wide variety of reports are available to them to keep track of day to day utilization and availability of critical COVID medicines and medical devices at village, block, district, state and central level. These datasets help MoHFW in data based decision support. This portal is integrated with CV analytics portal, NDMA, NIC data-hub, Arogyasetu, NCD, various State COVID19 portals."

1.21 Further during the same briefing by the representatives of Department of Pharmaceuticals held on 29.06.2021, the Committee also asked about the copy of the standard operating procedure (sop) that was issued by the central government to state governments to utilize Remdesivir, Tocilizumab, Amphotericin-B. In this regard, Department of Pharmaceuticals in their post evidence reply stated as below:

> "There was no standard operating procedure as such. States/UTs were however advised during every drug allocation letters to utilise the drug judiciously as per the National treatment Protocols.
>
> A. Remdesivir- Ministry of Health on 7th June 2021 has issued a separate 'Advisory on rational use of Remdesivir for COVID-19 treatment'. The same has also been hosted on website of MoHFW for wider dissemination (**Annexure-3**).
>
> B. Amphotericin B-Guideline for management of Mucormycosis in Covid-19 patients is issued by MoHFW. The scope of this document is to provide a guidance to clinicians (physicians/ respiratory physicians/ intensivists/ ENT surgeons etc.) to detect Mucormycosis at an early stage in patients who are hospitalised for treatment of Covid – 19 (as well as those discharged after treatment) and treat such patients optimally **(Annexure-5).**
>
> C. Tocilizumab- Clinical Management Protocol: Covid-19 issued by MoHFW on 24.5.2021 giving details about use of Tocilizumab in the Treatment of COVID-19 patients **(Annexure-4)."**

1.22 On being asked about any communications received from the States/UTs regarding inadequate supply/distribution of medicines and medical devices including Medical Oxygen and Oxygen Concentrators since 1 April, 2021 and steps that were taken to address their issues, the Department of Pharmaceuticals in their written reply stated as under:

> **"**Department of Pharmaceuticals (DoP) had received representations from States/UTs with respect to the drugs under DoP, allocation and few other drugs which were not allocated by DoP such as Colchicine, Antibody cocktail Casirivimab, Imdevimab etc. The States were regularly engaged with procurement of the allocated quantity of drugs while simultaneously all efforts were also made to augment the production and availability. The representations covered requirement of more quantity of drugs, non-supply by manufacturers etc. which were promptly acted upon/ replied by the Department of Pharmaceuticals."

1.23 During the above said briefing the Committee also highlighted that during the second wave states like Karnataka experienced shortfall in medicines due to less allocation of medicines like Remdesivir by the Central Government despite of spike in Covid cases. In this regard the Committee sought effective measures that are being taken to allocate critical Covid medicines and medical equipment to all the States/UTs in a fair

and equitable manner keeping in view the actual requirements for medicines due to spike in Covid cases in respective states:

> " DoP and MoHFW undertook the allocation of drugs where the mis-match is their supply and demand was observed in the initial days to ensure fair and equitable distribution of the drugs across the country. The drugs under allocation were Remdesivir, Tocilizumab and Amphotericin-B. The allocation however meant that the States/UTs were to place orders for the allocated quantity of drugs through their respective procurement process. The allocation has been discontinued for Remdesivir since 23.05.2021 and Amphotericin-B since 24.07.2021. Further, the MoHFW has put in place the Buffer Guidelines and shared the same with States/UTs on 13.07.2021whereby States/UTs are requested to immediately initiate the necessary procurement process on priority, and to place sufficient procurement orders for the essential drugs, with a view to ensure continuous availability of drugs during any possible future surg in cases. Further, the list of manufacturers and importers of COVID drugs with their contact details were also shared by DoP with the States/UTs on 21st July, 2021."

1.24 During the second wave, the medicines like Remdesivir, Tocilizumab, Amphotericin B were required in very high demand. In this regard the Committee asked to provide information on State/UT-wise allocation of these medicines and the number of patients actually recovered after usage of these medicines, medicine-wise, the DoP in their post evidence reply stated as under:

> "The allocation and supply of Remdesivir, Tocilizumab and Amphotericin B is given at **Annexure-6**. However, there is no data on the number of patients actually recovered after use of these medicines."

1.25 The Committee also asked about the corrective measures that are being taken to avoid the situation of non-availability of medicines, ICU beds, medical grade oxygen, medical devices etc. in future which had shaken the country during the sudden onset of second wave of pandemic , Department of Pharmaceuticals stated in their written reply that the following measures have been taken:-

> "As informed by Ministry of Health and Family Welfare, Public Health is a state subject falling under List II of the VII Schedule of the Constitution of India. Government of India supported the States and undertook a series of actions including further strengthening of existing health infrastructure to ensure availability of sufficient hospital beds, drugs, medical oxygen and other consumables to aid proper clinical care of COVID-19 patients in the States/ UTs. Some of the ongoing initiatives to strengthen hospital infrastructure include:-
>
> - With the intent to reduce the risk of cross infection to non-COVID patients as well as to maintain continuity of non-COVID essential health services in the country, a three- tier arrangement of dedicated COVID-19 health facilities [(i) COVID Care Center (CCC); (ii) Dedicated COVID Health Centre (DCHC) and (iii) Dedicated COVID Hospital (DCH)] has been implemented in the country.
> - Government of India, to supplement the hospital facilities, has roped in tertiary care hospitals under ESIC, Defence, Railways, paramilitary forces, Steel Ministry etc. Further, many large temporary treatment facilities were established by DRDO to manage surge in COVID-19 cases in the country.

- The isolation bed capacity and ICU bed capacity which was only 10,180 and 2,168 before the first lockdown (as on 23rd March 2020) is being enhanced continuously and is currently at 18,03,266 isolation beds and 1,24,598 ICU beds (as on 2nd August 2021).
- Till now State/UTs and Central Government institutions have been allocated 4.23 crore N95 masks, 1.77 crore PPE coveralls, 10.46 crore Hydroxychloroquine tablets. In addition, 49,246 ventilators have been supplied (as on 3rd August 2021).
- Taking note of spread of the disease to peri-urban and rural areas in many districts, Ministry of Health and Family Welfare on 16th May 2021 has issued an “SoP on COVID-19 Containment and Management in Peri-Urban, Rural and Tribal Areas" .
- With the intent to protect paediatric age group in current and any future surges of cases, Guidelines for management of COVID-19 in children were also issued on 18th June 2021. The guideline provides guidance on the management of acute presentation of COVID-19 as well as Multisystem Inflammatory Syndrome (MIS-C) in children and adolescents found temporally related to COVID-19 .

With regard to medical oxygen supplies, the following actions were taken:-

- Ministry of Health and Family Welfare closely monitored the availability and supply of Medical Oxygen and necessary infrastructure available with respective State/UTs for management of COVID-19 effectively.
- The daily Liquid Medical Oxygen (LMO) supply, which was about 1,292 MTs per day in February 2021 increased to 9,690 MTs in May, 2021. On 28th May 2021, a total of 10,250 MTs of LMO was allocated to the states. This was done by enhancement of LMO production in steel plants as well as in other LMO plants. Restrictions were imposed on industrial use of oxygen.
- To ensure equitable supply, a supply allocation plan for the high burden states was prepared by DPIIT in consultation with the States, Ministry of Steel, Ministry of Transport, All India Industrial Gases Manufacturers Association (AIIGMA) & other stakeholders. This was issued on 15th April 2021 and further revised on 18th April 2021.
- 1,02,400 oxygen cylinders were procured in the months of April and May of 2020 and distributed to States. Further orders for additional 1,27,000 cylinders have been placed on 21.04.2021 (54,000 jumbo cylinders (D type) and 73,000 regular cylinders (B type). Deliveries of the same have started and 73,352 (56,108 B-type and 14,244 D-type) cylinders have been delivered as on 3rd August 2021.
- To generate Oxygen at the health facility level, Pressure Swing Adsorption(PSA) plants are being established in each district hospitals, especially in far flung areas enabling the hospitals to become self-sufficient in generation of oxygen for their needs and thereby, reduce the burden on the medical oxygen supply grid across the country. As on 3rd August 2021, out of a total 1,222 allocated PSA plants, 283 have been commissioned.
- Ministry of Skill Development & Entrepreneurship, Indian Navy and IIT, Kanpur have developed a training program for the operation and maintenance of PSA plants and have identified and trained and around 2100 other trainees across the country.
- Norms have been issued on 6th July 2021 by the Ministry of Health & Family Welfare to all the States/UTs regarding the establishment of PSA plants/LMO tanks in Public and Private Health facilities.
- Further, to fast-track the availability of Medical Oxygen in rural and semi-urban areas, more than 39,000 oxygen concentrators have been allocated to various States.

- Guidance Note has been prepared and circulated to States by MoHFW on 8th June,2021 regarding oxygen concentrators in primary health facilities .
- With a view to increase the storage capacity of Liquid Medical Oxygen in the States, under the Emergency COVID Package Part-II, 1,050 Liquid Medical Oxygen Tanks along with Medical Gases Pipeline System (MGPS) each at a cost of Rs 80 Lakhs have been approved.
- All the States have been advised for rational use of oxygen and to cut down the wasteful usage by strict monitoring. The guideline on rational use of oxygen was issued last year on 25th September 2020. These were further revised and disseminated to States on 25th April 2021 (**Annexure-1**).

To ensure provisioning of drugs for managing COVID-19 cases in the country, the following actions were taken:-

- The monitoring of production and availability of drugs has been carried out as a joint exercise by DoP, NPPA under DoP and CDSCO under the Ministry of Health and Family Welfare (MoH&FW).
- Action is initiated at the National level to augment production of critical drugs including import besides support in terms of equitable distribution of the critical supplies.
- In order to augment domestic manufacturing capacities of Remdesivir, the accelerated approval of 40 additional manufacturing sites was granted by the CDSCO. The number of approved manufacturing sites has, accordingly, increased from 22 in mid-April, 2021 to 62 at present.
- The domestic production capacity of all the seven licensed manufacturers was augmented from around 38 lakh vials per month in April, 2021 to nearly 122 lakh vials per month in June, 2021.
- All States/UTs and State Drugs Controllers have been requested to verify stock of drugs and check other malpractices and take effective steps to curb hoarding and black marketing of some drugs like Remdesivir.
- Guidelines for Buffer Stock Management of COVID-19 were issued to all States/ UTs 13.07.2021 with the objectives of keeping the buffer stocks of drugs to expand and enhance capabilities to respond to any unforeseen surge in cases, to ensure continuous supply of drugs in such a scenario and to ensure equitable distribution across the country (**Annexure-2**).
- Pro-active steps to communicate with the medical fraternity by way of issuance of advisory for rational use of Remdesivir for COVID-19 treatment (23.04.2021) have been taken by MoHFW for benefit of all stakeholders.
- Regarding enhancing availability of Tocilizumab, CDSCO has granted approval for conduct of clinical trials to two applicants; so that the country may not be dependent entirely on imports and the supply position may further ease out.
- For Liposomal Amphotericin B, new licenses were granted by DCG(I) in favour of 11 new manufacturers during the months of May-June 2021 in addition to existing 5 manufacturers.
- The domestic production has also increased from 62,000 vials in April, 2021 to 3.45 lakh vials in July 2021. Similarly, quantities of imports have substantially increased from 26,165 in April, 2021 to 5.09 lakh in July 2021.

  States/UTs have been provided with periodic projected requirement of hospital infrastructure based on the then prevalent growth rates. Further, on COVID-19 India portal, all States and Districts were provided with a projection tool to calculate future requirements of hospital infrastructure and other logistics."

E. Preparedness For The Third Covid-19 Wave

1.26 During briefing on the subject, the Committee wanted to know about the preparedness for the next wave particularly on the predictions that the next wave may affect the children more unlike the other two waves. In this regard, the Secretary, DoP replied as below:-

> "Hon. Chairperson, I am very grateful for your query on this. Most of us have become workaholic and so when the number of cases came down, it is a good thing, we found that we do not have works. So, we have now started planning. Hoping that there would not be a third wave but we are planning for it. We have done it in the following way. We have been coordinating with the Health Ministry again to identify the drugs for which we should start preparing. Secondly, we are trying to get some estimation of the volumes of each drug that would be required. As you may appreciate that depends on forecasting the size and period of the so called third wave or future surge. So, since it is a forecast, it has got certain limitations. However, we have tried to take a scenario which is tenable and we had, as I mentioned, an administrative arrangement in the Drug Coordination Committee and the Empowered Group too. We are taking this to these committees and getting their validation of the volumes that we are looking at. Simultaneously, our DoP has started interacting with the manufacturers of these seven/eight drugs saying that probably this will be the demand whenever there is a third wave and what is your readiness to manufacture and supply at that time. Just to bring it to the notice of the hon. Committee, in the case of pharmaceutical products, our country is fortunate that there are no constraints of manufacturing capacity. The industries have sufficient manufacturing capacity. ….Madam, regarding the possibility of having a large number of paediatric patients, here again we are working in the realms of possibility. We do not know for certain. However, as I mentioned to you, some of the medicines which are more used for the children, we have already started identifying the manufacturers and started engaging with them for ramping up the production. We have requested the Director General of Health Services to tell us which are the medicines which will be required in the case of paediatric patients and he has provided that to us. We are now preparing an Action Plan. Our Joint Secretary is in-charge of it. He is preparing an Action Plan which will have manufacture-wise what is their production capacity, what is their availability of APIs, what are the binding constraints. We are preparing the Action Plan and it would be ready very soon. So, we will do it in a focussed manner."

1.27 Further when it was asked what specific steps are being taken by the Department for the creation of a buffer stock of medicines and medical devices essential for fighting COVID 19 in the wake of a third wave, Department of Pharmaceuticals in their post evidence reply furnished the following information :

> "On 18th June 2021, MoHFW has issued Guidelines for Management of COVID-19 in Children (below 18 years). Buffer Stock Management Guidelines for COVID-19 drugs have been prepared for guidance of the States/ UTs to build up buffer stocks of essential COVID drugs and to ensure their availability for addressing any future surge in COVID cases. The guidelines were communicated to States/ UTs vide MoHFW's DO Letter No X.11035/178/2021-DRS dated 13th July 2021 **(Annexure-2)**.
>
> A Scheme on "India Covid-19 Emergency Response and Health Systems Preparedness Package - Phase-II" (ECRP-Phase-II) during 2021-22 has been

approved by the Cabinet on 8.07.2021 for an amount of Rs. 23,123 crore, to be implemented in 9 months from 1st July, 2021 to 31st March, 2022. The Scheme is aimed to prevent, detect and respond to the continuing threat posed by COVID-19 and strengthen national health systems for preparedness in India. The scheme is a Centrally Sponsored Scheme (CSS) with some Central Sector (CS) components. One of the CSS components is support to the States for provision of required drugs and diagnostics for COVID management, including maintaining a buffer stock for essential medicines required for effective COVID-19 management. In this regard, Guidance Note on "India Covid-19 Emergency Response and Health Systems Preparedness Package - Phase-II" (ECRP-Phase-II) has been shared with the States/UTs on 14th July 2021**,** requesting the States to send the proposals for appraisal and approval. Further, the ECRP-II has also a CS component of Central Procurement of essential medicines (including the emerging drugs, based on the needs) for effective management of COVID19".

CHAPTER-II

STATUS OF AVAILABILITY OF MEDICINES AND MEDICAL DEVICES

A. Monitored Drugs

2.1 Department of Pharmaceuticals stated in its background note that the list of drugs required for the management of the COVID-19 emanates from the Clinical Treatment Protocols issued from time to time by the AIIMS/ ICMR-COVID-19 National Task Force or the Joint Monitoring Group of the MoHFW set up under the DGHS. The protocols keep getting updated based on the evidence of the effectiveness of the said drugs. However, there are also some drugs which are yet not listed in the clinical treatment protocol for COVID-19 but are prescribed by the physicians all over India and are in good demand. The list of drugs provided by ICMR during the DCC meeting is given below. The drugs mentioned in the list and observed to have likely supply-demand gaps are being monitored by the CDMC.

S.No.	Drugs	Current status
1.	Paracetamol – Syrup formulation, tab of 650 mg	In protocol
2.	Tab Dexamethasone all strengths	In protocol
3.	Methyl prednisolone – Injection	In protocol
4.	Methyl prednisolone – Tab	In protocol
5.	Prednisolone – Tab	In protocol
6.	Remdesivir	In protocol, optional
7.	IVIG	For pediatric patients
8.	Enoxaparin	In protocol
9.	Liposomal Amphotericin B	In protocol for mucormycosis
10.	Posaconazole	In protocol for mucormycosis
11.	Budesonide	In protocol
12.	Heparin	In protocol
13.	Ivermectin	In protocol
14.	Tocilizumab	In protocol
Not in protocol		
15.	Favipiravir	Not in protocol, used
16.	Aspirin	Not in protocol, used
17.	Itolizumab	Not in protocol, used
18.	Azithromycin	Not in protocol, used
19.	Doxycycline	Not in protocol, used
20.	Colchicine	Not in protocol, may be used
21.	Baricitinib	Not in protocol, may be used
22.	Molnupiravir	Not in protocol
23.	Monoclonal Antibodies	Not in protocol
24.	Interferon	Not in protocol

(a) Remdesivir

2.2 It is a patented drug, manufactured in India under voluntary licenses granted by Gilead Life Sciences USA, the patent holder, to seven Indian pharmaceutical companies. The domestic production capacity of all the seven licensed manufacturers was augmented from 38 lakh vials per month to nearly 122 lakh vials per month. With the accelerated approval of 40 additional manufacturing sites by the CDSCO, the number of approved manufacturing sites has increased from 22 to 62.

2.3 In this regard, when the Committee asked about the adequacy of augmented production of nearly 122 lakh vials per month to meet the emergent needs of the country in case of third wave of pandemic particularly considering large population size of the country, DoP stated in a written reply as under:

> "The present level of production is sufficient as of now since the manufacturers are not receiving enough orders for procurement of the drugs which indicates the low demand from the States/UTs and private hospitals. To meet the future demand, the buffer guidelines have been issued whereby the States/UTs have been asked to maintain the buffer stock of drugs by placing orders with the suppliers for any surge in COVID cases."

2.4 Department of Pharmaceuticals further informed the Committee that due to the sudden rise in demand for treatment of Covid-19 patients, Department of Pharmaceuticals and MoH&FW jointly undertook an exercise for allocation of the drug to all the States/UTs of the country in a move to ensure fair and equitable distribution across the country for an interim period till the ramping up of production takes place and the drug is adequately available in the market. The allocation plan was continuously revised based on enhanced availability of Remdesivir due to ramping up of production. The State/UT Governments were requested to appoint a Nodal Officer to coordinate with the Central Government as well as the manufacturers for better coordination of the supply issue as per allocations. Beginning with the first allocation to States/UTs on 21st April, 2021 to the seventh allocation made on 23rd May 2021, the total cumulative allocation of 98.87 lakh vials of Remdesivir was made to all States/UTs and Central Health Institutions covering the period from 21st April to 30th May 2021. Due to slowdown in the demand of Remdesivir from the States/UTs owing to decrease in the number of active cases and sufficient availability of the same in the market, it was decided by the Drug Coordination Committee to discontinue the allocation to States/UTs by the end of the May, 2021. A summary of the allocations mentioned above is shown in the Table below.

Summary of allocations of Remdesivir to States/UTs/Central Institutions

S. No.	Name of State/UT	Allocation Order dated 21st April 2021	Allocation Order dated 24th April 2021	Allocation Order dated 29th April 2021	Allocation Order dated 1st May 2021	Allocation Order dated 7th May 2021	Allocation Order dated 16th May 2021	Allocation Order dated 23rd May 2021
1	A & N Islands		1000	1000	2000	2000	3000	4000
2	Andhra Pradesh	58881	60000	69100	142100	235000	375000	541000
3	Arunachal Pradesh		1000	1000	2000	2000	4000	6000
4	Assam		7500	7800	13800	31000	60000	102000
5	Bihar	24604	40000	44500	87800	150000	200000	239000
6	Chandigarh		5000	5400	8900	13000	18000	22500
7	Chhattisgarh	48250	75000	80400	130900	200000	268000	325000
8	DNH and DD		1000	1400	3400	4000	5000	5000
9	Delhi	61825	72000	81300	150900	220000	280000	310000
10	Goa		3000	3500	10700	26000	49000	64000
11	Gujarat	163559	165000	182500	307000	419000	510000	575000
12	Haryana	29441	35000	40000	84800	149000	229000	273000
13	Himachal Pradesh		3000	3500	9300	24000	47000	70000
14	Jammu & Kashmir		10500	11000	20800	42000	78000	118000
15	Jharkhand	15417	21000	21800	46900	79000	106000	124000
16	Karnataka	25352	122000	139300	301300	575000	1000000	1425000
17	Kerala	16192	24000	29300	109300	200000	275000	375000
18	Ladakh		1000	1000	2000	2000	4000	5500
19	Lakshadweep		1000	1000	2000	2000	3000	4500
20	Madhya Pradesh	92411	95000	106700	189700	260000	323000	375000
21	Maharashtra	269218	435000	473500	809500	1157000	1492000	1766000
22	Manipur		1000	1000	2000	2000	6000	11500
23	Meghalaya		1000	1000	2000	2000	5000	10000
24	Mizoram		1000	1000	2000	2000	4000	6000
25	Nagaland		1000	1000	2000	2000	5000	8500
26	Odisha	11107	21000	21700	34700	73000	141000	218000
27	Puducherry		3000	3100	5100	11000	22000	37000
28	Punjab	13412	22000	25000	50000	85000	143000	196000
29	Rajasthan	26169	67000	73600	141600	248000	376000	478000
30	Sikkim		1000	1000	2000	2000	5000	7500
31	Tamil Nadu	58881	59000	67500	135500	205000	350000	560000
32	Telangana	21551	35000	41800	93800	145000	215000	247000

33	Tripura		1000	1000	2000	2000	5000	10000
34	Uttarakhand	13575	16000	18600	41600	74000	124000	173000
35	Uttar Pradesh	122833	161000	179300	336200	495000	625000	708000
36	West Bengal	27321	32000	38400	94400	160000	245000	350000
37	Central Govt. (MoHFW)			20000	70000	70000	70000	104000
38	Central Govt. (other than MoHFW)							33000
Total		**1100000**	**1600000**	**1800000**	**3450000**	**5370000**	**7670000**	**9887000**

2.5 All the seven licensed manufacturers have been supplying Remdesivir to States/UTs as per the allocation, both against the Government purchase orders and also through their private distribution channels in States/UTs and the supplies are being monitored actively by NPPA. A total of 92.79 lakh vials were supplied across the country during 21st April – 13th June, 2021. In addition to allocation mentioned above, a total of 6.44 lakh vials of Remdesivir, which have been received through donation from other countries/organizations and 1.50 lakh vials which have been commercially imported, have also been allocated to States and UTs. As mentioned earlier**,** allocations have also been made to the Central Health Institutions under MoHFW and other Ministries. A total of 99,746 vials have been supplied between 21st April – 30th May, 2021 against an allocation of 1,37,000 vials. NPPA has been continuously troubleshooting the supply side issues between the manufacturers and States on real time basis by liaising with the State/UT nodal officers and the manufacturers and ensuring smooth supplies across the country. The approach included:-

(a) Collecting daily reports on the supply from manufacturers.
(b) Regular meetings with the liaison officers (LOs) of the manufacturers.
(c) Close coordination with the nodal officers of the States/UTs.
(d) Proactive action based on the active cases.
(e) Seeking information on purchase orders placed by the States/UTs.
(f) Regular monitoring through email communications, phone calls, messaging apps, etc.

2.6 The Committee asked about the advisories that were issued to medical practitioners and to the public about the optional nature of use of Remdesivir for the treatment of COVID 19, Department of Pharmaceuticals in their written reply stated as under:

> "Ministry of Health & Family Welfare has issued Updated Detailed Clinical Management Protocol for adult cases of COVID-19 on 24th May 2021. Similarly, Guidelines for Management of COVID-19 in Children were also issued by MoHFW on 18th June 2021. Both these guidelines have been widely disseminated and are hosted on website of MoHFW. The clinical management protocol for COVID-19 clearly states that use of Remdesivir has been approved under Emergency Use Authorization, to be considered in only a select sub- group of patients with moderate to severe disease. Additionally, Union Ministry of Health on 7th June 2021 has issued a separate 'Advisory on rational use of Remdesivir for COVID-19

treatment' **(Annexure-3)**. The same has also been hosted on website of MoHFW for wider dissemination. Standard treatment guidelines have also been disseminated through MoHFW'sCenter of Excellence initiative with AIIMS, Delhi as the apex institution. This exercise is carried out with State level/Regional centres of excellence as well as private doctors to promote rational use of drug."

2.7 During the course of briefing held on 29.06.2021, the Committee observed that the Government should review the continuance of Remdesivir in Clinical Treatment Protocol though as it is not a lifesaving drug. It is just shortening the hospital stay by a few days and the drug manufacturers and hoarders made money during peak period. In this regard, Department of Pharmaceuticals in their post evidence written reply furnished the following clarification:

"As informed by Ministry of Health and Family Welfare, a few studies like 'Adaptive Covid-19 Treatment [GM1] Trial' found that Remdesivir is useful in cases of Covid 19 with SpO2<94% on room air (moderate to severe cases) if it is administered within 7 to 10 days of illness. Also, it has been noted that use of Remdesivir led to a shorter median time from randomization to recovery (10 days, vs. 15 days with placebo) and may have reduced the time to hospital discharge (12 days vs. 17 days). These studies and others like the SOLIDARITY Trial on the other hand, didn't show statistically significant improvements in overall mortality, initiation of ventilation, and duration of hospital stay. However, the COVID-19 clinical management protocol is being reviewed regularly based on evolving scientific evidence. Further to promote rational use of drug in select sub-group of patients only, the clinical management protocol for COVID-19 clearly states that use of Remdesivir has been approved under Emergency Use Authorization, to be considered in only a select sub-group of patients with moderate to severe disease.

Additionally, Ministry of Health on 7th June 2021 has issued a separate 'Advisory on rational use of Remdesivir for COVID-19 treatment'. The same has also been hosted on website of MoHFW for wider dissemination **(Annexure-3).** Standard treatment guidelines have also been disseminated through MoHFW'sCenter of Excellence initiative with AIIMS, Delhi as the apex institution. This exercise is carried out with State level/Regional centers of excellence as well as private doctors to promote rational use of drug."

2.8 As the country witnessed large scale suffering of public for buying Remdisivir due to its prescription by medical practitioners even though it is not in essential protocol, the Committee asked whether any inquiry was conducted in this matter. In this regard, Department of Pharmaceuticals in their written reply stated as below:

"Shortages of Remdesivir in market had been noticed in the months of April 2021 due to the sudden surge in demand of the drugs for managing COVID-19 patients. In order to substantially augment the production of Remdesivir, Drugs Controller General (India) granted expeditious approval to 40 new manufacturing sites of the licensed manufacturers of Remdesivir. This led to increase in number of Remdesivir manufacturing sites from 22 in mid-April to 62 at present. The domestic production capacity of Remdesivir increased from around 38 lakh vials per month in April, 2021 to around 122 lakh vials per month in June, 2021. Further, in order to augment domestic availability of Remdesivir manufactured in the country, the export of Remdesivir Injection and Remdesivir API (Active Pharmaceutical Ingredient) was prohibited from 11th April, 2021. In addition, DoP and MoHFW jointly undertook an

exercise for allocation of available stocks of Remdesivir to all the States/UTs of the country in order to mitigate shortage and to ensure fair and equitable distribution across the country. The total allocation and supply of the drug is given as under:

S. No.	Name of the drug	Allocation to States/ UTs and Central Institutions (in vials)	Supply till 12.09.2021 (in vials)
1.	Remdesivir Injection	98,87,000	1,06,55,345

In addition to the above allocation, on commercial supplies to States/UTs/Central Institutions (to be procured by the States/ UTs at their level), the MoHFW has also supplied around 30,10,798 Remdesivir vials, free of cost, to the States/UTs to address COVID pandemic. As on date, the demand of Remdesivir has come down considerably and the demand supply gap has reversed whereby supply is much more than the demand. Accordingly, Remdesivir was moved from Prohibited to Restricted Category of Exports on 14th June, 2021. The states and UTs have been issued "Guidelines for Buffer Stock Management of Covid-19 Drugs" **(Annexure-2)** and advised to procure and maintain buffer stocks of Remdesivir and other Drugs for preparedness to deal with any future requirements. As on date there is no shortage of Remdesivir reported by any States/UTs. Central Drugs Standard Control Organization (CDSCO) has requested all States/UTs Licensing authorities through several advisories to instruct their enforcement staff to keep strict vigil especially at sensitive places on attempts at black-marketing/hoarding of COVID drugs and to take stringent action against the offenders. As per information available from various State Licensing Authorities, various enforcement actions like seizure, arrests of accused persons / registration of FIR etc. have been carried out by the State Licensing Authorities."

2.9 The Department of Pharmaceuticals (DoP) in their background note stated that due to the sudden rise in demand for treatment of Covid-19 patients, the DoP and Ministry of Health and Family Welfare (MoH&FW) jointly undertook an exercise for allocation of the drug to all the States/UTs of the country in a move to ensure fair and equitable distribution across the country for an interim period till the ramping up of production takes place and the drug is adequately available in the market. In this regard, the Committee observed that as per allocation order dated 23rd May, 2021, Maharashtra was allocated 17,66,000 vials and Karnataka was allocated 14,25,000 vials whereas Tamil Nadu, Kerala and Andhra Pradesh which are also affected largely by the pandemic were allocated only 5,60,000 vials, 3,75,000 vials and 5,41,000 vials respectively. When asked about the reasons for less allocation of vials for the above-mentioned affected states when compared to Maharashtra and Karnataka, the DoP furnished the following reasons in their written reply:

"The allocation made on 23.05.2021 reflects the cumulative allocation done to States/UTs which was the result of individual allocations done on various past occasions. For instance, the cumulative allocation of 17,66,000 vials to Maharashtra was based on allocation done on 21.04.2021, 24.04.2021, 29.04.2021, 01.05.2021, 07.05.2021, 16.05.2021 and 23.05.2021. The process aDoPted for all States/UTs was similar."

2.10 Further the Committee also asked about the formula that is adopted for the equitable and fair allocation of vials to various States and Union Territories. In this regard,

Department of Pharmaceuticals in their written reply stated, "The drugs (Remdesivir) were allocated based on transparent and dynamic criterion such as oxygen demand and proportion of active cases. The allocation was made on weekly basis which enabled response to latest data of disease incidence in each state."

2.11 On being asked about the appointment of Nodal Officers by all the States/UTs to coordinate with the Central Government as well as the manufacturers for better coordination of the supply issue as per allocations, the Department of Pharmaceuticals in their written reply stated, **"**Yes. The Nodal officers appointed by the States/ UTs remained in touch with the Department of Pharmaceuticals for effective working of the allocation and supply of the drugs."

2.12 Having seen large-scale black marketing and exorbitant prices of Remdesivir medicine during peak period of second wave of pandemic, the Committee enquired about the steps that were taken by NPPA and Department of Pharmaceuticals and punitive action taken against black marketers as a result thereof. In this regard, Department of Pharmaceuticals in their written reply stated as below:-

> "CDSCO had requested all the States/UTs Licensing authorities through several advisories to instruct their enforcement staff to keep strict vigil especially at sensitive places and to take stringent action against the offenders by conducting special drive of monitoring and investigation. As per information available from various State Licensing Authorities, in cases of black-marketing/hoarding/overcharging of Covid management drugs, various enforcement actions like Drug seizure, Arrests of accused persons / registration of FIR etc. have been taken out by the State Licensing Authorities. As on 12.07.2021, 146 cases out of 317 cases of hoarding/black marketing/over-pricing of Remdesivir have been reported and actions (Drug seizure/ arrests/ notices issued) have been taken in by the respective State Licensing Authorities.
>
> Separately, NPPA vide letter dated 08.04.2021 addressed to all State Drug Controllers, had directed that the State Governments and UTs may closely monitor the production and availability of COVID-19 drugs to prevent black marketing and hoarding. It further directed to ensure that there is no violation of provision of DPCO, 2013 with regard to compliance of ceiling prices/permissible increase in prices of scheduled/non-scheduled formulations. NPPA had also set up a Control Room (Helpline No.-1800111255/ Email: monitoring-nppa@gov.in) to receive complaints on availability on medicines and is making all out efforts to address the issues promptly by coordinating with the State authorities, manufacturers, marketers and their associations. 6 complaints were received on overcharging of Remdesivir and 32 were on other COVID drug and medical devices during the second wave of COVID-19. These complaints were referred to the concerned State Drug Controller for necessary action. "

2.13 On being asked about public sector undertakings under the Department of Pharmaceuticals that have been granted license to manufacture Remdesivir so as to manufacture the quality medicine at a competitive price viz-a-viz private sector manufacturing, the Department of Pharmaceuticals in this regard stated as under:

"The public sector undertakings under the Department of Pharmaceuticals have not been granted license to manufacture Remdesivir as it is a patented drug and Gilead, the Patent holder, has not given voluntary license to such PSUs. Moreover, all the PSUs under the Department of Pharmaceuticals are either under the process of strategic sale or closure."

(b) <u>Tocilizumab</u>

2.14 According to the background note, Tocilizumab is being prescribed by the physicians across India to the hospitalized patients affected by COVID and it is also listed in the treatment protocol issued by the Joint Monitoring Group of MoHFW. The drug is not manufactured in India and is sourced from a company Roche in Switzerland. Cipla Ltd in India is the sole marketer of this drug in India. Till about March, 2021 the demand of Tocilizumab by various hospitals across the country was adequately being met until the sudden spike of COVID cases in April, 2021 onwards whereby the demand for the drug went up hugely.

2.15 In this regard, the Committee asked about the steps that are being taken for the import of adequate quantity of this medicine to meet any eventuality of sudden surge in cases in the form of third wave of the pandemic, the Department of Pharmaceuticals in their written note stated, " Department of Pharmaceuticals is in constant touch with the sole marketer company in India to source more quantity of the drug. MEA, through its mission in Switzerland, is also in regular touch with the Roche senior officials for sourcing more quantity of the drug for the country."

2.16 Department of Pharmaceuticals in their background note stated that the allocation of Tocilizumab was done based on the number of active cases to ensure a fair and equitable distribution. The States/UTs have to place orders for the allocated quantity with Cipla Ltd. The allocation and supply to States/UTs/Central Health Institutions, jointly done by Department of Pharmaceuticals and MoHFW so far is shown in the table below-

Tocilizumab	Allocation date	Total allocation (No of vials)	Supply as on 20th June, 2021
400 mg vial	30th April 2021 to States	9,900	9,548
	4th May 2021 to Central Govt Institutions		
	5th May 2021 to UTs		
80 mg vial	11th May 2021 to States/UTs and Central Health Institutions	65,000	44,136
	7th June 2021 to States/UTs and Central Health Institutions		

2.17 Tocilizumab was also donated on two occasions by Oman and the company Roche itself to the MoHFW. The quantities have been again distributed to the States/UTs and the Central Govt Hospitals and are shown below-

Tocilizumab	Allocation date	Total allocation (No of vials)	Supply completed
400 mg (Oman)	13th May, 2021 to States/UTs and Central Health Institutions	1,000	1,000
80 mg (Roche)	10th May, 2021 to States/UTs and Central Health Institutions	50,024*	25,211
**On 27th May, MoHFW decided to supply only 50% of it and remaining reserved for supply in future depending upon active case load.*			

2.18 The Department of Pharmaceuticals in their background note further informed that while making the allocations, the States/UTs have always been advised to use the drug in a very judicious and efficient manner. They have been also advised to widely publicize in their respective States/UTs the mechanism for the hospitals to obtain the drug from the State Health Departments. Further, CDSCO has also given approval to one Hyderabad based company named Hetero Ltd which has developed this drug to conduct the Clinical Trials. Once the Clinical Trials are over, the country may not be dependent entirely on imports and the supply position will further ease out.

2.19 In this regard the when the Committee asked about the details on emergency use approval if any given by CDSCO to the Hyderabad based company which has developed this drug for indigenous manufacturing in the country, DoP in their written reply furnished the following information:

> "As informed by Department of Health and Family Welfare, as of 6.08.2021, one Hyderabad based company viz., M/s Hetero Biopharma Limited submitted an application on 19.07.2021 for emergency use approval to indigenously manufacture and market Tocilizumab in the country based on the interim results of Phase III clinical trial in COVID-19 patients. Earlier M/s. Hetero Biopharma Limited was permitted conduct of multi-centric, Prospective, Double Blind, Randomized, Parallel Phase III clinical trial for evaluating the efficacy, safety and tolerability of Tocilizumab injection in Cytokine Storm of Severe Coronavirus Disease (Covid-19) Pneumonia (TOCICOVID Study) on 12.05.2021. This was based on the recommendations from the Subject Expert Committee of CDSCO at its meeting held on 11.05.2021 which recommended grant of approval to conduct phase-III Clinical trial. The firm presented the interim results before the 167th COVID-19 Subject Expert Committee in its meeting dated 22.07.2021. After detailed deliberation, the committee recommended that the firm should submit the safety and efficacy results of all patients enrolled in the trial as on date after completion of not less than 14 days after administration of the drug, along with the summary of the clinical data based on which the Emergency Use Authorization (EUA) was granted by US FDA for the RMP. Now, Hetero, on 6th September 2021 has conveyed that it has received restricted EUA from the Drug Controller of India (DCGI) to launch generic version of Tocilizumab.
>
> Further, another Hyderabad based firm viz., M/s CuraTeQ Biologics Private Limited has also submitted an application to conduct a randomized, open-label, parallel group Phase II study to compare efficacy and safety of Tocilizumab (BP08) plus

standard of care versus reference biologic Tocilizumab (Actemra/RoActemra) plus Standard of Care in Patients with Severe COVID-19 Disease. The protocol & firm's proposal was deliberated in the Subject Expert Committee's meeting dated 01.06.2021 to 03.06.2021, which recommended changes in the protocol. Further, the amended protocol was again deliberated in the Subject Expert Committee meeting dated 14.06.2021 which recommended grant of approval to conduct phase-II Clinical trial. However, the firm is required to manufacture the drug for use in clinical trial after obtaining NOC from RCGM (Review Committee on Genetic Manipulation)."

(c) <u>Amphotericin-B</u>

2.20 The Department of Pharmaceuticals in their background note stated that sudden increase in demand has been observed in some states for Amphotericin-B which is being actively prescribed by the physicians to patients suffering from Mucormycosis also known by the name Black Fungus, a post COVID complication. Amphotericin-B is of two types viz Liposomal and Conventional. The Liposomal variant of the drug is the preferred choice of physicians for treating patients of mucormycosis since the same is considered to be safe and is able to act on the body in a controlled manner with minimum side effects.

2.21 In this regard, when the Committee asked to furnish the details on the reasons for post COVID complication of Black fungus and exact causes of the disease, Department of Pharmaceuticals in their written reply stated as under:

"As informed by Department of Health and Family Welfare that Mucormycosis and other fungal infections, although not new diseases, are most commonly seen as opportunistic infection in patients with underlying risk factors. Advisories on Mucormycosis have been issued by ICMR, AIIMS, Delhi as well as DGHS, which point to a multifactorial causation of Mucormycosis in COVID-19 patients. Causal association has been observed between elevated blood sugar levels (whether in patients with pre-existing diabetes mellitus, or hyperglycaemia due to steroid therapy), immune-suppressive therapy, irrational use of steroids as well as broad spectrum antibiotics. A number of technical advisories and guidance have been issued by Ministry of Health & Family Welfare (MoHFW):

- An updated "Clinical Guidance on Diagnosis and Management of Diabetes at COVID- 19 Patient Management facility" was issued by MoHFW on 1st June 2021.
- Realizing the multi-disciplinary approach required to manage patients suffering from Mucormycosis and other fungal infections, a checklist for managing Mucormycosis and other fungal infections was circulated to all States/UTs on 11th June 2021.
- The clinical management guidelines for managing COVID-19 cases by MoHFW advocates rational use of steroids for managing moderate to severe cases of COVID- 19 under strict medical supervision.
- Noting the relationship between use of steroids and other immunosuppressive drugs, "Advisory for rational use of Steroids and Tocilizumab in the treatment of Covid -19 patients" was issued by Directorate General of Health Services (**Annexure-4)."**

2.22 On being asked about adequacy of the present level of production of this medicine to meet the present requirements of the country, including the number of companies

involved in production and their total monthly production capacity, Department of Pharmaceuticals stated in writing as below :

> **"**The present level of production of Liposomal Amphotericin B is sufficient as of now since the manufacturers are not receiving enough orders for procurement of the drugs which indicates the low demand from the States/UTs and private hospitals. To meet the future demand, the buffer guidelines have been issued by MoHFW whereby the States/UTs have been asked to maintain the buffer stock of drugs for any surge in Mucormycosis cases. The number of companies involved in production is 16 and their total installed monthly production capacity is about 7,74,200 vials."

2.23 Further the Committee asked about the steps that have been taken/being taken for the import of the drug to fill the gap between the requirement and production. In this regard, DoP in their written reply furnished the following information:

> "In order to ensure quick supply, foreign sources were immediately tapped with the help of MEA and various Indian Missions in foreign countries were alerted to look for sourcing the said drug from anywhere in the world. The largest foreign supplier is M/s Gilead, USA and M/s Mylan is sole marketer for the drug in India. In order to augment the availability of the drug through imports, MEA has played a very critical role in reaching out to various suppliers of either the finished formulation or the raw materials abroad. Further, vide OM dated 16.05.2021, MoHFW had requested the MEA to explore all possibilities of sourcing Amphotericin B/Liposomal Amphotericin B injection from abroad through Indian Missions. MEA has also been working on ensuring supplies of key excipient named HSPC and DSPG-Na from overseas suppliers for production of Liposomal Amphotericin B in India. As a result of the efforts undertaken, the import of the medicine has also increased."

2.24 The Committee also asked about the steps that are being taken for augmenting production capacity of this medicine in the country. It has been stated as under in the written reply furnished by Department of Pharmaceuticals:-

> "The Department of Pharmaceuticals and CDSCO continuously engaged with the manufacturers of drugs used for Mucormycosis. The CDSCO vide letter dated 07.05.2021 has issued letters to individual manufacturers of Liposomal Amphotericin-B to enhance their production capacity to cater to the increasing demand of the drug. Further CDSCO, after consultation with the association of Drugs manufacturers, issued manufacturing / marketing permission of Amphotericin B Liposomal Injection to eleven firms. On 17.5.2021, the CDSCO has also issued a circular whereby it reiterated its resolve to expeditiously process all applications of stakeholders wanting to manufacture drugs keeping in mind the emergent need of such drugs in the pandemic. CDSCO also called upon all State/UT Drug Controllers to bring the said circular to the attention of all the stakeholders. All applications submitted by companies for permission to manufacture Amphotericin-B have been considered expeditiously while keeping in mind the safety and efficacy of the drug to be manufactured.
>
> Further, the AIIMS/ICMR led National Task Force amended the protocol to include Conventional Amphotericin-B and Posaconazole to the bouquet of drugs which can be used to treat mucormycosis.

The supply side monitoring of the drugs was done by the NPPA to ensure expeditious availability by continuous follow up with suppliers and Nodal Officers of the States and UTs. NPPA monitored/coordinated the supplies to various States/UTs through active coordination between Liaison Officers (LOs) of the manufacturers/marketers and the Nodal Officers of States/UTs as per the allocation made by Department of Pharmaceuticals."

2.25 On being asked about the study/analysis that has been conducted by the Government of India to know the reasons for spike in black fungus cases in our country among Covid infected patients who were on artificial oxygen during their Covid treatment, Department of Pharmaceuticals furnished the following information in their written reply:

"Mucormycosis and other fungal infections, although not new diseases, are most commonly seen as opportunistic infection in patients with underlying risk factors. Advisories on Mucormycosis have been issued by ICMR, AIIMS, Delhi as well as DGHS, which point to a multifactorial causation of Mucormycosis in COVID-19 patients. Causal association has been observed between elevated blood sugar levels (whether in patients with pre-existing diabetes mellitus, or hyperglycaemia due to steroid therapy), immune-suppressive therapy, irrational use of steroids as well as broad spectrum antibiotics. Till date there is no scientific evidence to suggest increased risk of Mucormycosis for patients on oxygen therapy."

2.26 When the Committee enquired about the gap between the requirement and supply of Amphotericin B to various States/Union Territories during the months of April, May and June, 2021, Department of Pharmaceuticals stated in writing as below:

"The assessment of requirement of Amphotericin of various States/UTs is being ascertained from the number of patients of mucormycosis reported on the MoHFW portal. To ensure equitable distribution and till the time shortage of drug was noticed, allocation of the drug has been made to States/UTs."

2.27 Further, during the briefing held on 29.06.2021 the Committee asked about the steps that are being taken by Department of Pharmaceuticals to provide required quantity of Amphotericin B to the states where the Black fungus patients were increasing but the Government of India's supply was not commensurate with the requirements during the second of the pandemic as every patient is to be given five doses of medicine for about ten to twelve days or even more and steps that were taken/being taken for the equitable and fair distribution of available stock of the medicine as per the actual requirement of the States/UTs. In this regard Department of Pharmaceuticals in their post evidence written reply stated as under:

"The Department of Pharmaceuticals neither procures nor supplies drugs to State Governments. The procurement of drugs is to be done by the States themselves or by MoHFW. However, as an interim measure, to ensure equitable distribution of drugs in the country, Department of Pharmaceuticals and MoHFW jointly undertook the allocation of drug whereby the States/UTs were to place orders on the manufacturers for the allocated quantity and procure the drug. Simultaneously, the Department of Pharmaceuticals constantly worked with domestic manufacturers and importers to ensure the augmentation of supply of the drug so that the States/UTs are able to procure sufficient quantity of the drug."

(d) Medical Grade Oxygen

2.28 The Committee asked about the current level of production of medical grade oxygen in the country, capacity enhancement of medical grade oxygen, steps taken by the DoP to ensure adequate production and availability of medical grade oxygen in the country since the onset of the Covid pandemic in the country, the DoP in their written reply stated as under:

> "Government of India, along with the State Governments took all possible steps to tackle the unprecedented surge in oxygen demand that arose in the second wave of Covid-19.
>
> - Ministry of Health and Family Welfare closely monitored the availability and supply of Medical Oxygen and necessary infrastructure available with respective State/UTs for management of COVID-19 effectively.
> - Liquid Medical Oxygen (LMO) supply, which was about 1,292 MTs per day in February 2021 increased to 9,690 MTs in May, 2021. On 28th May 2021, a total of 10,250 MTs of LMO was allocated to the states. This was done by enhancement of LMO production in steel plants as well as in other LMO plants. Restrictions were also imposed on industrial use of oxygen.
> - In order to ensure equitable supply, a supply allocation plan for the high burden states was prepared by DPIIT in consultation with the States, Ministry of Steel, Ministry of Transport, AIIGMA & all stakeholders. This was issued on 15th April 2021 and further revised on 18th April 2021.
> - 1,02,400 oxygen cylinders were procured in April and May of 2020 and distributed to the States. Further orders for additional 1,27,000 cylinders have been placed on 21.04.2021 [54,000 jumbo cylinders (D type) and 73,000 regular cylinders (B type)]. Deliveries of the same have started and 73,352 (56,108 B-type and 14,244 D-type) cylinders have been delivered as on 3rd August 2021.
> - In order to generate oxygen at the health facility level, PSA plants are being established in each district hospital, especially in far flung areas enabling the hospitals to become self-sufficient in generation of oxygen for their needs and thereby, reduce the burden on the medical oxygen supply grid across the country. As on 3rd August 2021, out of a total 1,222 allocated PSA plants, 283 have been commissioned.
> - Ministry of Skill Development & Entrepreneurship, Indian Navy and IIT Kanpur have developed a training program for the operation and maintenance of PSA plants and have identified and trained and around 2100 other trainees have been trained across the country.
> - Norms have been issued on 6th July 2021 by the Ministry of Health & Family Welfare to all the States/UTs regarding the establishment of PSA plants/LMO tanks in Public and Private health facilities.
> - Further, to fast-track the availability of Medical Oxygen in rural and peri-urban areas, more than 39,000 oxygen concentrators have been allocated to various States.
> - Guidance note has been prepared and circulated to States by MoHFW on 8th June, 2021 regarding oxygen concentrators in primary health facilities.
> - With a view to increase the storage capacity of Liquid Medical oxygen in the States, under the Emergency COVID Package Part-II, 1,050 Liquid Medical Oxygen Tanks along with MGPS each at a cost of Rs. 80 Lakhs have been approved.

- States have been advised for rational use of oxygen and to cut down the wasteful usage by strict monitoring. The guideline on rational use of oxygen was issued last year on 25th September 2020. These were further revised and disseminated to States on 25th April 2021.
- A dynamic and transparent framework for allocation of medical oxygen in consultation with States/UTs and all the stakeholders such as relevant Ministries, manufacturers/suppliers of liquid oxygen etc. was prepared. Also, online digital solutions viz. Oxygen Demand Aggregation system (ODAS) and Oxygen Digital Tracking System (ODTS) have been developed to ascertain the demand for medical oxygen from all medical facilities and to track their transportation.
- Further, the States were provided with oxygen equipment such as oxygen cylinders, concentrators and Pressure Swing Adsorption (PSA) oxygen generation plants. A total of 4,02,517 oxygen cylinders have been procured/ are being procured and distributed to the States.
- 1,222 PSA Oxygen generation plants have been sanctioned. Out of these, as on 15th July, 2021, 237 plants have been commissioned. Apart from this, 295 PSA plants are being installed by different Ministries."

2.29 When the Committee enquired about the cases where low/compromised quality medical grade oxygen have been reported to Price Monitoring Resource Units (PMRUs) at state level/ National Pharmaceutical Pricing Authority (NPPA) level and effective action that has been taken on these complaints, Department of Pharmaceuticals in their written reply stated, "Quality of Drugs is monitored by CDSCO and SDCs. No case of low/compromised quality of medical grade oxygen has been reported to PMRUs and NPPA."

2.30 During the briefing on the subject by the representatives of Department of Pharmaceuticals held on 29.06.2021, the Committee observed that loss of lives occurred due to non-availability of medical oxygen at block and village level and enquired about the necessary steps that are being taken by the concerned Ministry/ Department of Pharmaceuticals in the matter. In this regard, Department of Pharmaceuticals provided the following information in their post evidence reply:

> "Health is a state subject. Detailed guidelines for reporting of deaths have been issued by Union Health Ministry to all States/UTs. Accordingly, all States/UTs report cases and deaths to Union Health Ministry on a regular basis. ICMR on 10th May 2020 issued 'Guidance for appropriate recording of COVID-19 related deaths in India .
>
> MoHFW vide letter dated 9th October 2020 has conveyed to States/UTs, WHO and ICMR guidelines on correct recording of COVID-19 related deaths in accordance with globally accepted ICD-10 classification and also urged states to undertake periodic death audits with the aim to improve quality of healthcare services by suitable corrective measures. States/UTs were also provided with a proforma for undertaking death audits in this regard.
>
> The COVID-19 management toolkit for District Collectors shared by Ministry of Health & Family Welfare on 2nd April 2021 with, states also highlighted the need for deaths audits and follow up action as one of the key monitoring parameters. 167 Central teams deployed to 33 states/UTs have also reiterated need for correct

recording of deaths and undertake periodic death audits. The data of deaths are obtained from States/UTs. As on 16th September 2021, a total of 4,43,928 deaths due to COVID-19 have been reported by States/UTs."

(e) Oxygen Concentrator

2.31 The Committee asked about the brands of Oxygen Concentrators that are being sold in the country and quality standards that are being prescribed for Oxygen Concentrators, the Department of Pharmaceuticals in their written reply stated as under:

"After the TMR notification dated 3.06.2021 for Oxygen Concentrators by NPPA, about 122 different brands reported to the Authority. CDSCO regulates quality, safety and performance of notified medical devices under the Drugs & Cosmetics Act and Medical Devices Rules 2017. Oxygen concentrator is presently not under the licensing system as per D&C Act, 1940 and Medical Devices Rules 2017. As per GSR 102(E) dated 11.02.2020, such product will be under licensing in a phase wise manner. Further, quality standards are prescribed under Medical Devices Rules, 2017. The Bureau of Indian Standards (BIS) looks after the standards of the various medical devices."

2.32 When asked about the number of public and private Pharmaceutical companies manufacturing medical grade oxygen and oxygen concentrators in India and steps that are being taken to entirely meet the requirements of the country through domestic production, DoP stated in writing as below:

"Oxygen Concentrator was under voluntarily registration regime w.e.f. 01.04.2020 and now under mandatory registration regime w.e.f. 01.10.2021. As per the available information with NPPA, 96 importers 12 manufactures have reported their price related data. As informed by Department of Health and Family Welfare, to fast-track the availability of Medical Oxygen in rural and peri-urban areas, it is planned to provide 1 lakhs Oxygen Concentrators to the CHCs, PHCs and SHCs including HWCs in the country under PM-CARES Fund, so as to bring medical management closer to people and ensure the availability of critical resource of Oxygen closer to the public. This support is over and above the routine oxygen support available at such facilities through other sources (like state governments, NHM, ECRP etc.).

Further, to fast-track the availability of Medical Oxygen in rural and peri-urban areas, more than 39,000 oxygen concentrators have been allocated to various States. Guidance Note has been prepared and circulated to States by MoHFW on 8th June, 2021 regarding oxygen concentrators in primary health facilities."

(f) Ventilators

2.33 The Committee asked about the production, requirement and availability of ventilators in the country is satisfactory and details regarding shortage of ventilators faced by Staes/UTs during the first and second wave of pandemic, DoP in their written reply furnished the following reply :

" As informed by Department of Health and Family Welfare that at the beginning of the COVID-19 pandemic in Feb-2020, India was dependent on high-end imported ventilators. To meet the need of States and Hospitals for ventilators, domestic production of ICU ventilators was encouraged. Based on the assessed requirement, orders for around 60,000 ventilators were placed for supply to State/ UTs. The details of major suppliers are as follows:

i. 30,000 ventilators by M/s. Bharat Electronics Ltd.
ii. 10,000 ventilators by M/s Agva Healthcare Ltd.
iii. 13,500 Ventilators by M/s Andhra Pradesh Medtech Zone (AMTZ) Ltd.
iv. 5,000 ventilators by M/s Jyoti CNC Ltd.

MoHFW has been supplying ventilators to the States/UTs based on the demand projected by the States/ UTs. The allocation to hospitals/ institutions within the States/ UTs is being made by them based on their assessed requirement in the hospitals, availability of required infrastructure in the hospitals, trained manpower to handle ventilators etc. As on 03.08.2021, MoHFW has supplied 49,246 ventilators to the States/ UTs."

2.34 On being asked about the prices regulation by NPPA under Drugs Price control Order, Department of Pharmaceuticals stated in writing as under:

"Ventilators have been notified by MoHFW as Drugs under D&C Act, 1940 w.e.f. 1st April 2020 and it is presently under voluntarily licensing regime of CDSCO for 42 months i.e. till September 2023. Ventilator is a non-scheduled Medical Device and under the DPCO-2013, manufacturer/importer of non-scheduled medical devices is at liberty to fix the maximum retail price launched by it, but cannot increase it by more than 10% during preceding 12 months."

2.35 During briefing held on 29.06.2021, the Committee asked about the steps that have been taken to impart training to doctors, junior doctors and technicians in proper operation of ventilators as several deaths occurred due to lack of trained technicians to operate the ventilators. In this regard, Department of Pharmaceuticals in their post evidence reply stated as follows:

"In order to train medical/Para-medical personnel who would be operating these ventilators, an extensive online training programme has been launched by MoHFW on 21.05.2021 where the manufacturers of ventilators are providing online training to all the States/UTs. Till 05.08.2021, total 17,292 Doctors, Para-medical Personnel/ ICU Technicians/ Bio-Medical Engineers of States and UTs have got trained."

CHAPTER-III

POLICY INTERVENTIONS

A. Drugs/Medical Devices Pricing

3.1 NPPA fixes the ceiling price of scheduled medicines specified in the first schedule of the Drugs (Prices Control) Order, 2013 (DPCO) in accordance with the provisions of the DPCO. All manufactures of scheduled medicines (branded or generic) have to sell their products within the ceiling price (plus applicable Goods and Services Tax) fixed by the NPPA.

A manufacturer of a non-scheduled formulation (branded or generic) is at liberty to fix the maximum retail price launched by it. However, as per the DPCO, the manufacturers of non-scheduled formulations are not allowed to increase the maximum retail price of such formulations by more than 10% per annum.

3.2 The Committee asked about the ways to regulate the prices of drugs/medical devices whose base minimum retail prices are way too higher than the paying capacity of the average person particularly in the cases of Covid medicines like Remdesivir and devices like Oxygen Concentrators by NPPA. In this regard, DoP in a written reply furnished the following information:

> "(i) NPPA fixes the ceiling price of scheduled medicines specified in the first schedule of the DPCO, 2013 in accordance with the provisions of the DPCO. All manufacturers of scheduled medicines (branded or generic) have to sell their products within the ceiling price (plus applicable Goods and Service Tax) fixed by the NPPA. A manufacturer of a non-scheduled formulation (branded or generic) is, however, at liberty to fix the maximum retail price launched by it. However, as per the DPCO, the manufacturers of non-scheduled formulations are not allowed to increase the maximum retail price of such formulations by more than 10% per annum.
>
> Due to proactive intervention of the government, MRPs of various brands that varied up to Rs 5,400/- per vial, have been reduced voluntarily by the major manufacturers/marketers of the Remdesivir Injection (lyophilized) to less than Rs 3,500/-. Exercising its extraordinary powers in public interest, NPPA vide notification dated 3rd June 2021 has capped the Trade Margin for Oxygen Concentrators at 70% on Price to Distributor (PTD) level. The revised MRP effective from 9th June 2021 on all the brands and specifications have been shared with the State Drug Controllers for strict monitoring and enforcement. NPPA has also capped the trade margin on Pulse Oximeter, Glucometer, BP Monitor, Nebulizer and Digital Thermometer at 70% vide notification dated 13th July, 2021."

(a) Remdesivir

3.3 Remdesivir is a non-scheduled formulation under DPCO 2013. For existing lyophilized injections, MRPs of various brands varied up to a max of Rs 5400/ per vial. On the intervention of the NPPA, the licensed manufacturers voluntarily chose to reduce the retail prices of Remdesivir to less than Rs 3500/vial. Accordingly, NPPA issued an Office Memorandum No. 37008/2021/Div.VI/NPPA dated 17th April 2021 indicating revised retail

prices and directed Drug Controllers of All States/UT Governments to ensure availability of the same at revised prices as shown in table below-

Table: Revised MRP of different brands of Remdesivir

S. No.	Name of Manufacturer	Brand Name	Old MRP (Rs)	Revised MRP (Rs)
1	Cadila Healthcare ltd	REMDAC	2800	899
2	Cipla Ltd.	CIPREMI	4000	3000
3	Syngene International Ltd	RemWin	3950	2450
4	Dr. Reddy's Laboratories Ltd.	REDYX	5400	2700
5	Mylan Pharmaceuticals Pvt. Ltd.	DESREM	4800	3400
6	Hetero Healthcare Limited	COVIFOR	5400	3490
7	Jubilant Generics Ltd.	JUBI-R	4700	3400

3.4 In this regard, when the Committee asked about the reasons for different prices of Remdesivir by different brands, DoP in a written submission stated as follows:

> "National Pharmaceutical Pricing Authority (NPPA) fixes the ceiling price of scheduled medicines specified in the first schedule of the Drugs (Prices Control) Order, 2013 (DPCO) in accordance with the provisions of the DPCO and all manufacturers of scheduled medicines (branded or generic) have to sell their products within the ceiling price (plus applicable Goods and Service Tax) fixed by the NPPA. On the other hand, a manufacturer of a non-scheduled formulation (branded or generic) is at liberty to fix the maximum retail price launched by it. However, as per the DPCO, the manufacturers of non-scheduled formulations are not allowed to increase the maximum retail price of such formulations by more than 10% during preceding 12 months. Remdesivir is a non-scheduled formulation and the manufacturer has liberty to fix its price. However, due to proactive intervention of the government, MRPs of various brands that varied up to Rs 5,400/ per vial, have been reduced voluntarily by the major manufacturers/marketers of the Remdesivir Injection (lyophilized) to less than Rs. 3,500/-."

(b) Amphotericin-B:

3.5 In respect of scheduled formulations, the ceiling prices are fixed as per the provisions of Drugs (Prices Control) Order, 2013 (DPCO). As per NLEM 2015, Amphotericin B Powder for Injection 50 mg in three variants i.e. conventional, lipid and liposomal are scheduled formulations. Accordingly, the present applicable ceiling prices are as given below in Table:

Table: Present applicable ceiling prices for Amphotericin

S. No.	Medicine	Strength and dosage form	Unit	Ceiling price (excluding GST) Rs.
1	Amphotericin B (Conventional)	Powder for injection 50 mg	Each pack	310.48
2	Amphotericin B (Lipid)	Powder for injection 50 mg	Each Pack	3213.07
3	Amphotericin B (Liposomal)	Powder for injection 50 mg	Each Pack	7484.24

(c) Heparin

3.6 Heparin is used as blood thinner and Heparin Injection 5000IU/ ml has been considered as an essential COVID plus medicine and widely used for COVID-19 treatment. The Active pharmaceutical Ingredient (API) of this drug is imported from China. For this drug, NPPA received representations from several manufacturers mentioning that there is an upward increase in prices of API of this drug. Heparin Injection 5000IU/ ml, being under ceiling price, the increase in API prices posed a challenge for continued availability of this important drug. NPPA got the issue examined through Export-Import Monitoring Committee constituted by NPPA to inform impact on API pricing. The Committee reported 200% increase in landing cost of Heparin API and on its recommendation, NPPA revised the ceiling price of Heparin upward for a period of six months in June 2020 to ensure its continued availability during the pandemic. The same has been extended till 30.09.2021.

(d) Medical Oxygen

3.7 Medical Oxygen is not only an essential life-saving drug but critical for COVID management. Looking at the situation of COVID-19 and consumption trends of Medical Oxygen in the Country, MoHFW delegated powers to NPPA to enable necessary steps under clause (l) of subsection (2) of the section 10 of Disaster Management Act, 2005 to immediately regulate the availability and pricing of the Liquid Medical Oxygen (LMO) & Medical Oxygen in Cylinders. After extensive deliberation, NPPA, in exercise of extra ordinary powers, conferred by paragraph 19 of the Drug, (Prices Control) Order, 2013 and powers conferred under section 10(2)(l) of Disaster Management Act, 2005, in public interest, capped the price of Liquid Medical Oxygen (LMO) and the Oxygen Inhalation (Medicinal gas) in September 2020 for six months, which has subsequently been extended till 30.09.2021. Timely intervention by NPPA eased the situation of Medical Oxygen availability throughout the country, especially in distant and far-flung areas.

(e) Oxygen Concentrators

3.8 Department of Pharmaceuticals in their background note stated that NPPA in June 2020 and May 2021 has collected price related information from manufacturers/ importers

of Pulse Oximeters and Oxygen Concentrators. Due to global demand–supply mismatch and related issues, the prices of the Oxygen Concentrators have shown substantial volatility. Based on the request from the Ministry of Health and Family Welfare (MoH&FW), Government of India in its letter dated 18th May 2021, and the observations of Hon'ble High Court of Delhi relating to Orders dated 17.05.2021, a Stakeholder Consultation was held on 19th May 2021 through video conferencing to discuss the issues related to monitoring availability and pricing issues of COVID essential medical equipment and in particular oxygen concentrators.

Based on recommendation of Standing Committee on Affordable Medicines and Health Products (SCAMHP), NITI Aayog, NPPA vide Gazette Notification dated 03.06.2021 has capped the Trade Margin for Oxygen Concentrators at 70% considering current PTD as base for a period of six months till November 2021. Downward revision in price up to of 54% has been reported in 70 products/brands, showing reduction in MRP up to Rs. 54,337 per unit. Further, 58 brands have reported price reduction up to 25% and 11 brands between 26-50%. Out of 252 products/brands reported, 18 products/brands reported by the domestic manufacturers did not show any decline in prices.

The revised MRP effective from 9th June 2021 on all the brands and specifications have been shared with the State Drug Controllers for strict monitoring and enforcement. The relevant instructions are available on NPPA's website (www.nppa.gov.in). In order to monitor availability, the manufacturers / importers of Oxygen Concentrators have been directed to submit monthly stock details.

3.9 On being asked about the average price of a quality oxygen concentrator in the market, the Department of Pharmaceuticals in their written reply stated that the average price of oxygen concentrators, as reported by NPPA, after Trade Margin rationalisation vide NPPA notification dated 09.06.2021, is as follows:

Capacity	**Price range of Oxygen Concentrators as on 09.06.2021 (Rs.)**
Portable-5LPM	29,468 - 2,47,533
Portable-7LPM	50,000 - 68,544
Portable-8LPM	64,000 - 1,69,999
Portable-9LPM	69,400 - 1,00,800
Portable-10LPM	59,000 - 2,70,000
Stationary-5LPM	47,600 - 1,73,240
Stationary-7LPM	61,236 - 1,15,000
Stationary-8LPM	60,480 - 1,63,693
Stationary-10LPM	70,000 - 2,66,980

3.10 The Committee also asked about the reasons for high price of Oxygen Concentrators (OCs) and different prices of various brands of OCs, DoP stated in wring as under:

"Oxygen Concentrators are non-scheduled medical devices under voluntary licensing framework. As per consultation held with Oxygen Concentrators manufacturers and Industry Associations in May 2021, prices of Oxygen Concentrators have shown high volatility due to factors like currency fluctuation, increase in freight charges and non-availability of imported raw materials like zeolite, pumps, metal/plastic sheets, and medical electronic components etc. Further, the prices of Oxygen Concentrators depend on various characteristics like flow rate/ capacity, oxygen purity level, battery runtime/ backup etc. However, NPPA has considered flow rate/capacity to categorize the Oxygen Concentrators for the purpose of price analysis and trade margin rationalisation leading to reduction in prices."

3.11 On being asked about the action that has been taken/being taken against those companies which have not adhered to the NPPA notification capping the trade margin of OCs, Department of Pharmaceuticals in its written submission stated, "As informed by NPPA that they issued instructions to SDCs to monitor revised prices. As of now, no overcharging case has been reported with respect to Oxygen Concentrators".

B Policy Interventions In Tax and International Trade Policies

3.12 Department of Pharmaceuticals had also informed the Committee that the Government of India has made policy interventions both in the tax policy and the international trade policy in an effort to ease out the availability of the drugs. The following are the interventions done by Directorate General of Foreign Trade (DGFT) with regard to the international trade policy-

(a) Imposing prohibition on the export of Remdesivir formulation and Remdesivir API on 11th April, 2021. The prohibition was in place till 14th June, 2021 when the export policy of the drug was amended from Prohibited to Restricted. This ensured that the entire domestic production of the drug serves the domestic population till such shortages are there.
(b) On 1st June, 2021 the export policy of Amphotericin-B was amended by placing the same from free category to restricted category. The amended policy is still in place.

The following are the interventions made by the Department of Revenue with regard to the tax policy-

(a) Basic Customs Duty exemption was notified vide Notification 27/2021 dtd 20.04.2021 for Remdesivir injection, Remdesivir API and Beta Cyclodextrin (SBECD). The exemption will be in place till 31st October, 2021. Vide Corrigendum dtd 30.04.2021 the BCD exemption was also notified for Inflammatory Diagnostic (marker) kits, namely-IL6, D-Dimer, CRP (C-Reactive Protein), LDH (Lactate De-Hydrogenase), Ferritin, Pro Calcitonin (PCT) and blood gas reagents.
(b) Vide Notification 28/2021 dtd 24.04.2021 Basic Customs Duty and Health Cess on import of oxygen, oxygen related equipment and COVID-19 vaccines was exempted up to 31st July, 2021 which was later extended till 31st August, 2021.

(c) Vide Notification 31/2021 dtd 31.05.2021 Basic Customs Duty on import of Amphotericin-B was exempted up to 31st August, 2021.

(d) Vide Adhoc exemption order No 05/2021-Cus dtd 31.05.2021 the exemption from IGST on specified COVID-19 relief material donated from abroad, was notified up to 31st August, 2021.

(e) On the GST side, the GST Council in its 44th Meeting decided to reduce the GST rates which were notified on 14th June, 2021. The current rate and the reduced rate is shown in the table below-

		Current Rate	***Reduced Rate***
A. Medicines			
1	Tocilizumab	5%	Nil
2	Amphotericin B	5%	Nil
3	Anti-Coagulants like Heparin	12%	5%
4	Remdesivir	12%	5%
5	Any other drug recommended by Ministry of Health and Family Welfare (MoHFW) and Dept. of Pharma (DoP) for Covid treatment	Applicable Rate	5%
B. Oxygen, Oxygen generation equipment and related medical devices			
1	Medical Grade Oxygen	12%	5%
2	Oxygen Concentrator/ Generator, including personal imports thereof	12%	5%
3	Ventilators	12%	5%
4	Ventilator masks / canula / helmet	12%	5%
5	BiPAP Machine	12%	5%
6	High flow nasal canula (HFNC) device	12%	5%
C. Testing Kits and Machines			
1	Covid Testing Kits	12%	5%
2	Specified Inflammatory Diagnostic Kits, namely D-Dimer, IL-6, Ferritin and LDH	12%	5%
D. Other Covid-19 related relief material			
1	Pulse Oximeters, incl personal imports thereof	12%	5%
2	Hand Sanitizer	18%	5%
3	Temperature check equipment	18%	5%
4	Gas/Electric/other furnaces for crematorium, including their installation, etc.	18%	5%
5	Ambulances	28%	12%

3.13 Apart from the reduction of GST on Oxygen Concentrators, ventilators, pulse oximeters, hand sanitizers, temperature check equipment etc. for which DoP is responsible for availability. When the Committee asked about the status with respect to

adequacy, availability, accessibility and affordability of these medical equipments as they play very crucial role in COVID management, the DoP in a written submission stated as below:

> "NPPA has regulated the price of Oxygen Concentrator using Trade Margin Rationalization Approach up to 70% on Price to Distributor (PTD) by invoking the provisions of Para 19 of DPCO, 2013 vide notification no. S.O. 2161(E) dated 03.06.2021. Similarly, vide notification dated 13.07.2021, the Trade Margin up to 70% on Price to Distributor (PTD) level on Pulse Oximeter, Blood Pressure Monitoring Machine, Nebulizer, Digital Thermometer and Glucometer has been capped."

3.14 DoP in their background note also stated that Central Drugs Standard Control Organization (CDSCO) is undertaking feedback survey from Chemist Shops in thirteen states for 14 drugs with the help of field level offices. In this regard, when the Committee asked about feedback survey by Price Monitoring Resource Units (PMRUs) at state level/ National Pharmaceutical Pricing Authority (NPPA) at centre from PMBJP Kendras/district hospitals/consumers regarding availability of drugs/medical devices/equipments, DoP furnished the following information in their written reply:

> **"**CDSCO, through its Zonal and Sub-zonal offices conducts survey on availability of Hydroxychloroquine, Enoxaparin, Methyl Prednisolone (MP), Paracetamol, Dexamethasone, Budesonide, Ivermectin, Naproxen, Doxyxycline, Azithromycin, Prednisolone, Favipiravir, Amphotericin B and Apixaban at chemist shops in various location on every Monday. This is being shared with DoP/ NPPA for their required intervention, which is being carried out on regular basis.
>
> In addition, NPPA in co-ordination with 18 PMRUs has been conducting the weekly availability survey since May, 2021 for nine scheduled formulations and six non-scheduled formulations used for COVID management, on a sample basis. With effect from 5th July 2021 onwards in the weekly survey, PMRUs are also collecting information on availability of five essential devices for diagnostic purposes, in general and specially for COVID management viz., (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, and (v) Glucometer."

C. Enforcement Against Overcharging/ Spurious Medicines / Medical Devices

3.15 While briefing the Committee on the subject, the Secretary, Department of Pharmaceuticals during power point presentation furnished following information:-

- Regular enforcement actions by DCGI against black marketing /overcharging of COVID drugs like Remdesivir, Tocilizumab, Amphotericin B, Oxygen Cylinder etc. through the State Drug Controllers, local police, etc.

- Till 21st June 2021, out of total of 741 enforcement activities were undertaken in various places across the country
- 249 cases actions like filing cases/ lodging FIRs, arresting people involved in such activities, etc. have been taken

- 492 cases were those where no action was warranted.

- Ministry of Consumer Affairs vide letter dated 13.05.2021 addressed to Controller of Legal Metrology stated that it is required to ensure that no pre-packaged commodities including the drugs (like Remdesivir, etc) and medical device (like oxygen concentrators, cylinders etc) are charged over and above the MRP by sellers.

3.16 Having noted that the buyer is able to lodge a complaint against company/ chemist through Pharma Jan Samadhan (http://www.nppaindia.nic.in/redressal.html) in case of any ceiling price violation, the Committee asked about the number of complaints that have been received by NPPA via this mode during the first and Second wave of COVID19 pandemic and action taken on them. In this regard, DoP provided the following written reply:

> "Three (3) complaints have been reported by NPPA via Pharma Jan Samadhan during first and second wave of COVID 19 pandemic and necessary actions have been taken on such complaints as per the provisions of DPCO, 2013."

3.17 On being asked about the number of cases of overcharging/ spurious medicines/medical devices were reported to NPPA/PMRUs from the onset of Covid pandemic in March 2020 till date, Department of Pharmaceuticals in their written reply stated, “Since March 2020 till date NPPA has identified 1,009 cases of suspected overcharging in respect of scheduled formulations, Non-scheduled formulations and Medical Devices".

3.18 Further on being asked about the effective steps that are being taken on these complaints and alternative course of action or reforms made by NPPA to prevent similar situation in future, the Department of Pharmaceuticals in their written reply stated as under:

> "NPPA has issued Preliminary Notices (PNs) to those companies where suspected overcharging cases under the provisions of DPCO, 2013 have been identified. The replies received from the companies are at different stages of examination and in some cases Show Cause Notices/Demand Notices have been issued. In addition, NPPA undertook an analysis of the Form-V regarding seventeen (17) COVID Management Drugs in respect of companies registered in Integrated Pharmaceutical Database Management System (IPDMS). The analysis was conducted for (i) verification of suspected violation of Ceiling Prices in respect of Scheduled drugs; and (ii) verification of violation of increase in MRP beyond 10% under the provisions of Para 20 of DPCO, 2013 in respect of Non-scheduled formulations. Preliminary Notices (PNs) have been issued in 38 + 4 cases (total 42 cases), where suspected violation/ overcharging have been identified. NPPA has set up a Control Room and receives complaints on non-availability on medicines/overcharging etc. Most of the overcharging cases pertain to overcharging by chemists and are referred to SDCs for further necessary action."

Progress Made In Manufacturing Of Vaccines

3.19 Department of Pharmaceuticals in their post evidence reply also furnished information about the steps that have been taken for manufacture of vaccines by units other than Bharat Biotech and Serum Institute given as under:

"As informed by Department of Biotechnology that to support vaccine manufacturing in India, the Government of India has launched 'Mission COVID Suraksha- the Indian COVID-19 Vaccine Development Mission', being implemented by Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Undertaking (PSU) of Department of Biotechnology (DBT). Under the Mission, clinical trial lot manufacturing of promising vaccine candidates including: DNA vaccine candidate (Zydus Cadila); mRNA vaccine candidate (Gennova Biopharmaceuticals); intranasal vaccine candidate (Bharat Biotech) is being supported. Further, as part of efforts for augmentation of Covaxin production, capacity enhancement of Bharat Biotech and 3 Public Sector Enterprises (PSEs) including Haffkine Biopharmaceutical Corporation Ltd, Mumbai; Indian Immunologicals Limited (IIL), Hyderabad and Bharat ImmunologicalsBiologicals Limited (BIBCOL), Bulandshahr; is being supported. Also, technology transfer of Covaxin production to Consortium of partners including Hester Biosciences and OmniBRx Biotechnologies Pvt Ltd, led by, Gujarat Biotechnology Research Centre (GBRC), DoP of Science and Technology, Govt. of Gujarat is being facilitated by the DoP of Biotechnology. These efforts are expected to enhance the production of Covaxin from the present 1 Cr. doses per month to 10 Cr. Doses per month in the coming months. Additionally, 30 Cr. doses of the protein subunit vaccine candidate of Biological E, which is currently in phase III clinical trials, have been pre-ordered by Government of India. Also, Biological E has entered into a collaboration with Johnson & Johnson to manufacture the single dose adenovirus vectored vaccine under the Quad arrangement through technology transfer.

As informed by D/o H&FW, initiatives have been taken to accord high priority for review of proposal on fast track basis-

- As per office order dated 15.04.2021, the COVID Vaccines already approved by CDSCO for restricted use in emergency situation in India, and proposed to be fill finished at a site within the country different from the manufacturing site, by receiving bulk of the approved vaccine, will also be approved by CDSCO based on inspection & CDL release. Additionally, if such a vaccine is manufactured in India from basic drug substance stage to the fill-finish stage, it will also be given manufacturing licensee, based on inspection, for stock piling & CDL release.
- On the basis of said policy, CDSCO has granted permission for manufacture of Gam-COVID-Vac Combined vector vaccine (SPUTNIK-V) using Ready to fill bulk to M/s Ra (biologicals) Panacea Biotec Ltd., New Delhi for restricted use in emergency situation on 02.07.2021 and manufacturing license was issued on 05.07.2021.
- A revised Guidance was issued on 01.06.2021 for approval COVID-19 Vaccines in India for restricted use in emergency situation which are already approved for restricted use by US FDA, EMA, UK MHRA, PMDA Japan or which are listed in WHO Emergency Use Listing (EUL) in pursuance of fresh recommendations of National Expert Group on Vaccine Administration for COVID-

19 (NEGVAC). In this guidance, to further ease approval process, based on scientific rationale, for above mentioned vaccines, which are approved under EUA and has been established by immunizing millions of people were exempted even from pre & post approval bridging trial. Further, they were exempted from compulsion of every batch being tested by CDL, Kasauli, if it has been released/certified by National Control Laboratory (NCL) of country of origin. However, every such batch will continue to be released by CDL, Kasauli based on NCL certificate of country of origin and summary lot protocol. Further, assessment of safety in first 100 beneficiaries for 7 days prior rolling out for further immunization will continue.

- On the basis of said policy, CDSCO has granted permission for import of mRNA 1273 COVID-19 vaccine (Moderna) to M/s Cipla Ltd. Mumbai on 29.06.2021.
- Further, for augmentation of production capacity, CDSCO has granted permission to M/s Bharat Biotech, Bangalore facility and M/s Indian Immunological Limited, Hyderabad for manufacturing of Whole Virion Inactivated Corona Virus (COVAXIN) Bulk Vaccine and M/s Bharat Biotech, Ahmedabad facility for manufacturing of Whole Virion Inactivated Corona Virus (COVAXIN) Bulk and Vaccine for examination, test and analysis purpose.

- Also, CDSCO has granted permissions to manufacture COVID-19 vaccines to the following manufacturers other than M/s Bharat Biotech and M/s Serum Institute for the purpose of examination, test and analysis as follows:

1. M/s Cadila Healthcare Ltd.
2. M/s Panacea Biotec Ltd
3. M/s AurobinDoPharma Ltd.
4. M/s Reliance Life Sciences.
5. M/s Cadila Pharmaceutical Ltd.
6. M/s ShilpaBiologicalsPvt. Ltd.
7. M/s Gland Pharma Limited
8. M/s Wockhardt Limited
9. M/s StelisBiopharmaPvt. Ltd.
10. M/s Premas Biotech Pvt. Ltd.
11. M/s Indian Immunolgicals Ltd.
12. M/s VaxigenLifesciencesPvt. Ltd.

Considering the emergency and unmet need, Ministry of Health & Family Welfare (MoHFW) has issued notification vide G.S.R. 1511(E) dated 18.05.2020 under Section 26B of the Drugs and Cosmetics Act,1940 providing that manufacturer can manufacture and stock any vaccine for COVID-19, which is under clinical trial, for sale or distribution after completion of clinical trial and grant of manufacturing approval by CDSCO. In this regard, three manufacturers namely M/s Hetero Pharma, M/s Cadila Healthcare and M/s Biological E apart from M/s Bharat and M/s Serum were granted manufacturing licenses for manufacturing of COVID-19 vaccines for the stockpiling in the clinical trial stage for faster availability of COVID-19 vaccines for vaccination programme upon receipt of manufacturing license. Further, Ministry of Health and Family Welfare has notified vide S.O no. 4206 (E), dated 24.11.2020 and vide S.O. 2609 (E) dated 28.06.2021, National Institute of Biologicals (NIB), Noida and National Centre for Cell Science (NCCS), Pune

respectively in addition to its existing functions to perform the function of Central Drugs Laboratory as an additional testing facility in respect of COVID-19 vaccine.

3.20 During the briefing the Committee also asked about the present status of functioning of Vaccine manufacturing unit in Chengalpet, Tamil Nadu and its capacity to manufacture vaccines, the Department of Pharmaceuticals in their post evidence reply stated as under:

"As per D/o HFW, approval of the Cabinet Committee on Economic Affairs (CCEA) for the Integrated Vaccine Complex (IVC) project was granted in the year 2012. The project was conceptualized for manufacture and supply of the vaccines for Universal Immunization Program (UIP) of GoI. The requisite technology sourcing for manufacture of vaccines did not materialise as per the plan due to various factors and IVC is still in project mode. Since the DoE decided not to consider the proposal to revise the project cost to Rs. 879.02 crore in PIB, approval of the CCEA was requested to engage with potential COVID manufacturers/suppliers and other vaccine manufacturers for a commercial partnership through a transparent process for operationalization of the IVC. Accordingly, HLL issued a notification inviting Expression of Interest (EoI) on 16th January 2021 from Vaccine/ Pharmaceutical manufacturers for use of HBL's existing facilities at Integrated Vaccines Complex, Chengalpattu, on "as is where is basis" for production of COVID-19 /other vaccines with last date of submission as 29th January, 2021.

As HLL / HBL did not receive any bids within the original due date, the bid submission date was extended multiple times. The ultimate extended date for submission of bid ended on 21st May 2021 and despite relaxation of tender conditions mentioned above no party submitted bid for using IVC in response to the tender. IVC/HBL has three filling lines at various stages of mechanical completion and validation. IVC has a fill-finish capacity of 1000 to 1600 Million Doses as liquid vaccines with 5-Dose, 10-Dose and 20-Dose combinations with currently established 4 Filling Lines.

Efforts are on with potential vaccine manufacturers for operationalization of the unit. A reference was received from Government of Tamil Nadu for taking out the plant. The Government of Tamil Nadu was informed that Government of India is taking all steps to operationalize the unit at the earliest."

New Delhi;
16 March, 2022
25 Phalguna 1943 (Saka)

KANIMOZHI KARUNANIDHI
Chairperson,
Standing Committee on
Chemicals and Fertilizers.

OBSERVATIONS/RECOMMENDATIONS

RECOMMENDATION No-1

Availability of required quantum of medicines

The Committee note that the Department of Pharmaceutical's (DoP) mandate is the industry promotion for pharmaceutical industry and also providing support to the Ministry of Health and Family Welfare in achieving the objective of affordable, universal and quality health services in the country. DoP, therefore, undertakes the task of making the essential COVID related drugs available across the country in active partnership with the manufacturers of these drugs. The listing of drugs for the COVID management and including the same in the National Treatment Protocol is done by the Ministry of Health and Family Welfare (MoHFW). However, there are drugs which even though not in the National Treatment Protocol are also prescribed by the physicians across the country and are in high demand. Accordingly, based on the inputs received from MoHFW from time to time, Department of Pharmaceuticals has been working to augment the production and supply of the essential drugs required for management of COVID. The Department of Pharmaceuticals also submitted that it has no role in framing of National Treatment Protocol as currently Central Drugs Control Organisation (CDSCO) is updating the MoHFW about the production capacity and availability of the drugs. The Committee are of the strong view that even a single COVID patient from any corner of the country should not be deprived of timely medicines and medical devices for recovering from COVID 19. Since COVID 19 creates waves after waves, it is very much necessary to accord top priority to make timely availability of required quantity of medicines and medical devices to all the States and Union Territories. The Committee, therefore, recommend that :-

(a) daily review of requirements of all the States/UTs should be conducted by DoP and MoHFW in coordination with the State/UT Governments and continuous necessary steps should be taken for making available all the medicines and medical devices required for COVID 19 treatment as per the day to day requirements of all the States/UTs;

(b) the manufacturers of COVID medicines should be provided all kinds of support including logistics, regulatory facilitation by CDSCO, assistance in imports of raw materials through Ministry of External Affairs and Indian Missions abroad, relief in taxation etc. so as to enable them manufacture the required quantum of medicines.

(c) the Department of Pharmaceuticals should be made part of National Treatment Protocol so that coordination between DOP and MOHFW is initiated at the very planning stage itself.

RECOMMENDATION No-2

Major constraints in ensuring availability of medicines

The Committee note that there were two major constraints noticed in ensuring the availability of drugs in the initial few days of the surge of COVID cases. One was the lag time between manufacturing of the drug and its actual availability in the market because when they start manufacturing a drug like Remdesivir takes two to four weeks before the drug can come out because it is a biological process or a bio-chemical process. This time period is required with respect to the regulatory procedures which have a bearing on the safety and efficacy of the drug. In this regard the Committee note that MoHFW has brought out a buffer policy vide which the States/UTs have been advised to maintain adequate buffer stocks of the drugs and that the Central Government is also maintaining a buffer stock of the drugs. Second constraint was the import of certain raw materials for drugs, including the

finished formulations like Tocilizumab which is not manufactured in India. Even if APIs are domestically produced in the country, there are a few raw materials called excipients for which the country is depending on foreign manufacturers. In this regard, the Committee note that the Ministry of External Affairs provide assistance to all the manufacturers by coordinating with the overseas suppliers through Indian Missions abroad. Even though the steps have been taken by the Government to address these two constraints, the Committee make the following recommendations to ensure the availability of COVID medicines to the people at the time of surge in COVID cases:-

(a) Central Government should continuously maintain a buffer stock of all the medicines required for the treatment of COVID 19 and that a transparent and fair process should be adopted for the equal distribution of medicines and medical devices to meet the day-to-day requirements of each State and Union Territory.

(b) Immediate attention should be paid to address the issue of dependence on other countries for the raw materials particularly the excipients required for the production of COVID 19 related medicines. All necessary measures should be initiated on war footing for the manufacture of APIs and excipients in the country to end the dependence on other countries.

(c) Ministry of External Affairs (MEA) should continuously impress upon its missions abroad to provide the necessary assistance to the Indian manufacturers in getting the raw materials including excipients from the overseas suppliers for the manufacture of COVID 19 drugs. Secondly, Indian missions should play a strong role for the import of required quantum of medicines like Tocilizumab which are not manufactured in the country. Functioning of Indian missions in this regard should be reviewed in the meetings of Drugs Coordination Committee (DCC) and corrective measures

should be taken through MEA in case of any shortcomings in the functioning of Indian Missions. This recommendation of the Committee should be sent to the Ministry of External Affairs for its information and necessary action.

RECOMMENDATION No-3

Covid Drugs Management Cell (CDMC)

The Committee note that a COVID Drugs Management Cell (CDMC) has been set up in the Department of Pharmaceuticals (DoP) to oversee the management of smooth supply of drugs used in COVID-19 management during the pandemic. As per the information provided by DoP, daily morning meetings of CDMC are conducted to review and prioritize the actions required with respect to the issues surrounding drug production and availability. Looking at the importance and the quantum of work, the Department of Personnel and Training (DoPT) attached one Additional Secretary and five Directors with DoP who were then assigned specific tasks in DoP. Since the new strains of SARS COV 2 virus are emerging from various parts of the world and continuously affecting the population of the world including the people of our country on a large scale, the Committee would like to make the following recommendations:-

(a) In view of the continuous onslaught of the pandemic, CDMC should continuously function in DoP till the pandemic is entirely over.

(b) In case of necessity of more senior officers for reviewing the requirements of individual States/UTs, DoPT should be impressed upon posting the requisite number of Officers and staff for the effective functioning of the Cell. This recommendation may also be shared with DoPT for the purpose.

(c) Daily review meetings of CDMC should continue till the pandemic is entirely over.

(d) CDMC should work with the moral responsibility of ensuring that every COVID 19 patient in the country gets his/her COVID medicines and medical devices for the timely recovery from the disease.

(e) It should be the responsibility of CDMC to ensure fair allocation and distribution of medicines and medical devices to all the States and Union Territories by adopting transparent and fair criteria.

(f) COVID Drugs Management Cell (CDMC) at the centre alone is not sufficient and similar COVID Drugs Management Cells need to be created at State/UT level so that holistic monitoring as well as availability and distribution of medicines/medical devices is ensured in each State/UT. Necessary steps may be taken in this regard and the progress made may be conveyed to the Committee.

RECOMMENDATION No - 4

<u>Drugs Coordination Committee (DCC)</u>

(a) The Committee note that in order to formalise the inter-Departmental consultations on the issues with regard to drug availability, a Drugs Coordination Committee (DCC) was constituted vide OM 20.05.2021 as an institutional mechanism with representation from DoP, MoHFW, Directorate General of Health Services (DGHS), Indian Council of Medical Research (ICMR), Directorate General of Foreign Trade (DGFT), Ministry of External Affairs (MEA), CDSCO and NPPA for efficient decision making on all the issues with respect to COVID-19 related drugs. The Committee further note that Drugs Coordination Committee (DCC) in its meetings deliberated on issues such as the need to build up a buffer stock of drugs, regulating exports of COVID drugs and coordinating with manufacturers for ramping up production so as to be in a state of preparedness for drug supply in the event of a future surge. In this regard, the Committee feel that the success of this

administrative arrangement depends on the effective implementation of decisions taken by the Drugs Coordination Committee (DCC) as well as effective coordination among all the concerned Ministries/Departments and the State/UT Governments. The Committee, therefore, strongly recommend that an institutional mechanism should be created for the effective implementation of all the decisions of DCC by the concerned Ministries/Departments.

(b) According to DoP, DCC is an administrative arrangement for coordination till the time it is required and this mechanism will be used as and when required. Since various strains of COVID 19 are emerging in the world and the waves after the waves of the pandemic is affecting our country as well, the Committee, therefore, recommend that DCC should continuously function till the COVID 19 pandemic is completely over and its meeting should be held regularly for coordinating the efforts of various Ministries/Departments to make available the medicines and medical devices required for COVID 19.

RECOMMENDATION No - 5

Empowered Group-2(EG-2)

(a) The Committee also note that the Ministry of Home Affairs (MHA) vide its Order dated 29th May, 2021 has re-constituted Empowered Group-2 (EG-2) for Emergency Response Capabilities with Secretary, MoHFW as the Convener and 12 other Members of various Ministries/Departments of Government of India and the Prime Minister Office including the Secretary, DoP as a member for decisively and effectively addressing evolving changes from COVID-19 and for Emergency Response Capabilities. The subject "medicines" is tasked to the EG-2 besides Hospital beds with ICU and essential medical equipment for COVID. The Committee further note that EG-2 had prepared the buffer Stock Management Guidelines for COVID-19 drugs for the guidance of the States/ UTs to build up buffer stocks of

essential COVID drugs and to ensure their availability for addressing any future surge in COVID cases. The guidelines were communicated to the States/ UTs by MoHFW on 13th July, 2021. In this regard, the Committee are of the strong view that mere preparation and circulation of buffer stock guidelines is not adequate and it is equally important that the guidelines are followed by states and Union Territories in letter and spirit. The Committee, therefore, recommend that concrete measures should be taken for the availability of buffer stock of various medicines and medical devices with each and every State/UT so as not to deprive a single patient the medicines and medical devices required by her/him for the treatment of COVID 19.

(b) The Committee note that EG-2 is tasked with the decisions on import and export of essential COVID medicines such as Remdesivir, Liposomal Amphotericin B, Tocilizumab and IVIG. Since the country is again facing surge in number of cases, EG-2 reconsider its earlier decisions on permission granted for the export of these medicines and suitable decisions should be taken for the availability of these medicines to the people of the country. EG-2 also ramp up its efforts to import the medicines like Tocilizumab, Liposomal Amphotericin B etc. which are mostly imported for use in the country so that the requirements of the country are fulfilled.

RECOMMENDATION No - 6

<u>Joint exercise undertaken by the Department of Pharmaceuticals (DoP), National Pharmaceuticals Pricing Authority (NPPA) under Department of Pharmaceuticals and the Central Drugs Standards Control Organisation (CDSCO)</u>

The Committee note that for monitoring of production and availability of medicines for Covid related drugs there is a joint exercise undertaken by the Department of Pharmaceuticals (DoP), National Pharmaceuticals Pricing Authority (NPPA) under Department of Pharmaceuticals and the Central Drugs Standards

Control Organisation (CDSCO) under the Ministry of Health and Family Welfare (MoH&FW). The CDSCO plays an important role in giving approvals for manufacturing, marketing and distribution of the drugs and enforcement of drug licenses under the Drug and Cosmetics Act, 1940. Hence, CDSCO identifies the manufacturers of COVID drugs. Further, the major existing manufacturers of COVID drugs are also identified by NPPA through a database of retail sales where the manufacturers having largest market share of COVID drugs are identified. Once the manufacturers are identified, their production and supply are monitored weekly by NPPA and CDSCO apart from some detailed monitoring on three specific drugs viz. Remdesivir, Tocilizumab and Amphotericin-B. NPPA interacted regularly with Nodal Officers of States/ UTs and manufacturers to coordinate supplies. CDSCO, through its Zonal and Sub-zonal offices conducts survey on availability of Hydroxychloroquine, Enoxaparin, Methyl Prednisolone (MP), Paracetamol, Dexamethasone, Budesonide, Ivermectin, Naproxen, Doxyxycline, Azithromycin, Prednisolone, Favipiravir, Amphotericin B and Apixaban at chemist shops in various locations on every Monday. This is being shared with Department of Pharmaceuticals/ NPPA for their required intervention, which is being carried out on regular basis. In addition, NPPA in co-ordination with 18 PMRUs has been conducting the weekly availability survey since May, 2021 for nine scheduled formulations and six non-scheduled formulations used for COVID management, on a sample basis. With effect from 5th July 2021 onwards in the weekly survey, PMRUs are also collecting information on availability of five essential devices for diagnostic purposes, in general and specially for COVID management viz., (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, and (v) Glucometer. Both CDSCO and NPPA are engaged in collection of information on availability of medicines and medical devices in the market. However, the country witnessed chaos during the initial phase of the second wave due to non availability

of medicines/medical devices and their black marketing and this caused severe hardships to COVID 19 patients and their relatives. In this regard, the Committee feel that the Government should not allow re-occuurence of that kind of situation again. The Committee, therefore, strongly recommend that Joint Monitoring exercise by DoP, NPPA and CDSCO should be further strengthened so that the requirements of every state and union territory for the medicines and medical devices is properly assessed and necessary steps be taken to make available the required quantum of medicines and medical devices to effectively fight the COVID 19 pandemic. For the purpose, the representatives of CDSCO and NPPA should be included in the COVID Drugs Management Cell (CDMC) under the Department of Pharmaceuticals for the monitoring of the production and availability of medicines/medical devices in a holistic manner so as to initiate concrete measures to ensure the availability of required quantum of medicines/medical devices for the management of COVID 19 .

RECOMMENDATION No - 7

<u>Shortage of Remdesivir during the second wave of pandemic</u>

(a) The Committee note that Remdesivir which is a patented drug, manufactured in India by 7 Indian pharmaceutical companies under voluntary licenses granted by Gilead Life Sciences USA (patent holder). This drug has been included in the National Treatment Protocol of COVID 19 as an optional drug only. During second wave of the pandemic, shortage of this medicine caused severe hardships to the people across the country. DoP has taken steps to address the shortages of Remdesivir in the market that was noticed in the months of April 2021 due to the sudden surge in demand of the drugs for managing COVID-19 patients. The Department stated that in order to substantially augment the production of Remdesivir, Drugs Controller General (India) granted expeditious approval to 40 new manufacturing sites of the licensed manufacturers of Remdesivir. This has led

to increase in number of Remdesivir manufacturing sites from 22 in mid-April 2021 to 62 at present. The domestic production capacity of Remdesivir increased from around 38 lakh vials per month in April, 2021 to around 122 lakh vials per month in June, 2021. Further, in order to augment domestic availability of Remdesivir manufactured in the country, the export of Remdesivir Injection and Remdesivir API (Active Pharmaceutical Ingredient) was prohibited from 11th April, 2021. In addition, DoP and MoHFW jointly undertook an exercise for allocation of available stocks of Remdesivir to all the States/UTs of the country in order to mitigate shortage and to ensure fair and equitable distribution across the country. MoHFW has also supplied around 30,10,798 Remdesivir vials, free of cost, to the States/UTs to address COVID pandemic.In the aftermath of the second wave, the demand for Remdesivir has come down considerably and the demand supply gap has reversed whereby supply is much more than the demand. Accordingly, Remdesivir was moved from Prohibited to Restricted Category of Exports on 14th June, 2021. The states and UTs have been issued "Guidelines for Buffer Stock Management of Covid-19 Drugs" and advised to procure and maintain buffer stocks of Remdesivir and other Drugs for preparedness to deal with any future requirements. Since Remdesivir has been included in the National Treatment Protocol as only an optional drug, the Committee recommend that scientific studies should be conducted on the effectiveness of medicines like Remdesivir which have been included in National Treatment Protocol as optional medicines in curing critical COVID patients. Based on the studies, steps should be taken by MoHFW to remove those drugs which are not necessary for inclusion in the National Treatment Protocol.

(b) Affordable COVID-19 medicines and Medical devices is the need of the hour during these unprecedented Pandemic situation when the common man on the street is suffering either due to non availability of Remdesivir or if available, an exorbitant price is charged making it difficult for the poor people to afford the

medical treatment. However, the Committee fail to understand that none of the Pharma Public Sector Undertakings under the Department of Pharmaceuticals have been granted voluntary license to manufacture Remdesivir and other COVID essential drugs for public health supply. In this regard, the Committee feel that equal opportunity should also be extended to these Pharma PSUs who have developed trust, quality and cost effectiveness in their pharma products over a long period of time. The Committee, therefore, recommend that the Department of Pharmaceutical initiate steps to explore the possibilities of manufacturing of COVID essential drugs by PSUs under it.

RECOMMENDATION No - 8

<u>Nationwide Training Programme for Rational Use of COVID treating medicines</u>

The Committee note that the clinical management protocol for COVID-19 clearly states that use of Remdesivir has been approved under Emergency Use Authorization, to be considered in patients with moderate to severe disease so as to ensure rational use of Remdesivir in only select sub-group of patients. Additionally, Ministry of Health and Family Welfare has issued a separate 'Advisory on 7th June 2021 on the rational use of Remdesivir for COVID-19 treatment'. According to this advisory, every hospital needs to set up a Special Drug Committee (SDC) which must review the use of Remdesivir in their hospital periodically and SDC should preferably have a Pharmacology Professor/ faculty as a member wherever available. SDC should share their findings with the physicians periodically to ensure rational and judicious use of Remdesivir. Standard treatment guidelines have also been disseminated through MoHFW's Center of Excellence initiative with AIIMS, Delhi as the apex institution. This exercise is carried out with State level/Regional centers of excellence as well as private doctors to promote rational use of drug. Since the prescription of Remdesivir was rampant during the

second wave of COVID-19 pandemic rather than its prescription only in select sub-group of patients with moderate to severe disease. This created a hue and cry situation in the entire country due to severe shortage in availability of this medicine. Since it is very much necessary to educate the medical practitioners on the rational prescription/use of medicines/medical devices for the treatment of COVID 19, the Committee recommend that the Union Government in collaboration with the State Governments should organize nationwide online training programmes for all registered medical practitioners whether in Government or Private hospitals on the rational use of Remdesivir and other COVID drugs included in National Treatment Protocol.

RECOMMENDATION No - 9

<u>Prompt Action Against Hoarding/Black Marketing/Over Pricing of Medicines and Medical Devices</u>

(a) The Committee are concerned to note the large-scale black marketing of Remdesivir in particular and other medicines and medical devices in general at exorbitant prices during peak period of second wave of COVID-19 pandemic. This created a panic situation among public and led to huge crisis in availability of COVID-19 related medicines and medical devices. According to the Department of Pharmaceuticals, Central Drugs Standard Control Organisation (CDSCO) had requested all the States/UTs Licensing authorities through several advisories to instruct their enforcement staff to keep strict vigil on over pricing and black marketing. As per information available from various State Licensing Authorities, in cases of black-marketing/hoarding/overcharging of COVID-19 management drugs, various enforcement actions like drug seizure, arrests of accused persons / registration of FIR etc. have been taken out by the State Licensing Authorities. As on 12.07.2021, 146 cases out of 317 cases of hoarding/black marketing/over-pricing of Remdesivir have been reported and actions (Drug seizure/ arrests/ notices

issued) have been taken by the respective State Licensing Authorities. Separately, NPPA vide its letter dated 08.04.2021 addressed to all State Drug Controllers, had directed that the State Governments and UTs may closely monitor the production and availability of COVID-19 drugs to prevent black marketing and hoarding. It further directed to ensure that there is no violation of provision of DPCO, 2013 with regard to compliance of ceiling prices/permissible increase in prices of scheduled/non-scheduled formulations. NPPA had also set up a Control Room to receive complaints on availability on medicines and is making all out efforts to address the issues promptly by coordinating with the State authorities, manufacturers, marketers and their associations. NPPA had received 6 complaints on overcharging of Remdesivir and 32 complaints on other COVID drug and medical devices during the second wave of COVID-19. These complaints were referred to the concerned State Drug Controller for necessary action. In this regard, the Committee feel that very less number of complaints were registered with State Licensing Authorities and NPPA than the actual number of such indulgences of overpricing/hoarding/black marketing throughout the country. This clearly implies that there is very less awareness among people about the present complaint/grievance redressal mechanism. The Committee, therefore, recommend that the Union Government particularly CDSCO and NPPA should take appropriate steps for the stepping up of awareness among the people about the availability of complaint/grievance redressal mechanism so as to ensure that all such cases of overpricing/hoarding/black marketing come to the lime light.

(b) The Committee also strongly recommend that prompt action should be taken against hoarding/black marketing/over pricing of medicines and medical devices related to COVID-19 in all States/UTs in a time bound manner. CDSCO and NPPA should obtain monthly/fortnightly reports from the State Governments/UTs on the action taken against violators.

RECOMMENDATION No-10

Effective price control of Non-schedule COVID-19 related Medicines and Medical Devices

The Committee note that the National Pharmaceutical Pricing Authority (NPPA) fixes the ceiling price of scheduled medicines specified in the first schedule of the Drugs (Prices Control) Order, 2013 (DPCO) in accordance with the provisions of the DPCO and all manufacturers of scheduled medicines (branded or generic) have to sell their products within the ceiling price (plus applicable Goods and Service Tax) fixed by the NPPA. On the other hand, a manufacturer of a non-scheduled formulation (branded or generic) is at liberty to fix the maximum retail price launched by it. However, as per the DPCO, 2013 the manufacturers of non-scheduled formulations are not allowed to increase the maximum retail price of such formulations by more than 10% during preceding 12 months. According to the Department of Pharmaceuticals, Remdesivir being a non-scheduled formulation, the manufacturer has liberty to fix its price. However, due to proactive intervention of the government, MRPs of various brands of Remdesivir that varied up to Rs 5,400/ per vial have been reduced voluntarily by the major manufacturers/marketers of the Remdesivir Injection (lyophilized) to less than Rs. 3,500/-. Since waves after waves of the COVID 19 pandemic is hitting the world including our country, it is mandatory that the prices of all the COVID 19 medicines and medical devices are controlled by the Government so as to make them affordable for the common man. The Committee, therefore, recommend that the Department of Pharmaceuticals and NPPA to frame a new price control regime specific for Medicines and Medical Devices for COVID Management where the distinction between the scheduled and non-scheduled drugs may be done away with and all such medicines and medical devices are put under price control with no annual increase in prices allowed till the pandemic is entirely over in the country. The Committee hope the Department of

Pharmaceuticals and NPPA will understand the gravity of the situation and will take immediate necessary action on this recommendation within a stipulated time frame and will inform the Committee about the same in the action taken replies.

RECOMMENDATION No-11

India Covid-19 Emergency Response and Health Systems Preparedness Package - Phase-II

The Committee note that a Scheme on "India Covid-19 Emergency Response and Health Systems Preparedness Package - Phase-II" (ECRP-Phase-II) during 2021-22 has been approved by the Union Cabinet on 8.07.2021 for an amount of Rs. 23,123 crore, to be implemented in 9 months from 1st July, 2021 to 31st March, 2022. The Scheme is aimed to prevent, detect and respond to the continuing threat posed by COVID-19 and strengthen national health systems for preparedness in India. The scheme is a Centrally Sponsored Scheme (CSS) with some Central Sector (CS) components. One of the CSS components is support to the States for provision of required drugs and diagnostics for COVID management, including maintaining a buffer stock for essential medicines required for effective COVID-19 management. In this regard, the Committee note that a guidance Note on ECRP-Phase-II was shared with the States/UTs on 14th July 2021, requesting the States to send the proposals for appraisal and approval. Further, the ECRP-II has also a CS component of Central Procurement of essential medicines (including the emerging drugs, based on the needs) for effective management of COVID19. Presently the country is going through another wave of the pandemic and the threat of Omicron and the other strains of COVID virus is also looming large over the country. In this regard, the Committee appreciate that the Union Government is implementing the scheme ECRP-Phase-II with an amount of Rs. 23,123.00 crore. It is very much necessary that both CSS and CS components of the Scheme are implemented in letter and spirit. Since the Scheme is under implementation since 1st July, 2021, the

Committee hope that considerable progress would have been made in the implementation of both the CSS and CS components of the Scheme. In this regard, the Committee recommend that all the States/UTs should be given equal opportunities in getting the financial support under the Scheme for the provision of required drugs and diagnostics for COVID management, including maintaining a buffer stock for essential medicines required for effective COVID-19 management. As the Scheme is to be implemented by 31 March, 2022, the Committee should be informed of the assistance provided to each State/UT under the CSS component of the Scheme. The Committee should also be informed of the present status of implementation of the CS component of Central Procurement of essential medicines (including the emerging drugs, based on the needs) for effective management of COVID19.

RECOMMENDATION No-12

<u>Risk to children from COVID 19</u>

The Committee note with concern that Children are also at huge risk of getting COVID 19. So it is necessary that specific and fool proof preparedness is required with respect to the availability of medicines and medical devices specifically used for the treatment of COVID-19 positive children. In this regard, Ministry of Health and Family Welfare (MoHFW) has issued Guidelines for Management of COVID-19 in Children (below 18 years) on 18 June 2021. Just issuing guidelines is not enough and the Union Government should coordinate with all the State Governments/Union Territories for the effective implementation of these guidelines. Particularly the availability of adequate stock of IVIG should be reviewed with every State Governments/UTs. In case of inadequate buffer stock of IVIG with any of the states/UTs, the Union Government should take immediate necessary steps for the provision of required quantum of IVIG to those States/UTs. The action taken in this regard should be intimated to the Committee.

RECOMMENDATION No-13

Effective Research for better understanding of causes of Mucormycosis/ Black Fungus disease

The Committee note that there was a significant increase in number of cases of Mucormycosis (Black Fungus) in Covid – 19 patients during the second wave of the pandemic. According to the Department of Health and Family Welfare, Mucormycosis and other fungal infections, although not new diseases, are most commonly seen as opportunistic infection in patients with underlying risk factors. Causal association has been observed between elevated blood sugar levels (whether in patients with pre-existing diabetes mellitus, or hyperglycaemia due to steroid therapy), immune-suppressive therapy, irrational use of steroids as well as broad spectrum antibiotics. As per the submission made by the Department of Pharmaceuticals, till date there is no scientific evidence to suggest increased risk of Mucormycosis for patients on oxygen therapy. The Committee further note that advisories on Mucormycosis have been issued by ICMR, AIIMS, Delhi as well as DGHS, which point to a multifactorial causation of Mucormycosis in COVID-19 patients. A number of technical advisories and guidance have also been issued by Ministry of Health & Family Welfare (MoHFW) viz. Advisory for rational use of Steroids and Tocilizumab in the treatment of Covid -19 patients. Since it is very much necessary to ascertain the exact cause of Mucormycosis, the Committee recommend that the virology research institutes in the country should ramp up their research on the causes of fungal infections like Mucormycosis/Black Fungus that is prevalent in COVID-19 patients for better understanding and management of medicines and medical devices required for such patients. Indian Council of Medical Research (ICMR) may also be engaged in this regard for finding the appropriate reasons for fungal infections like Mucormycosis in critical post COVID-19 patients.

RECOMMENDATION No-14

Treatment for Mucormycosis/Black Fungus disease

The Committee note that Amphotericin-B, which is used for the treatment of Mucormycosis, is of two types viz Liposomal and Conventional. The Liposomal variant of the drug is the preferred choice of physicians for treating patients of Mucormycosis since the same is considered to be safe and is able to act on the body in a controlled manner with minimum side effects. During second wave of the pandemic, the country faced shortage of this medicine. The Government of India's supply was not commensurate with the requirements of the States during the second wave of the pandemic as every patient is to be given five doses of medicine for about ten to twelve days or even more than that. The number of companies involved in production of Amphotericin-B is 16 and their total installed monthly production capacity is about 7,74,200 vials. Further CDSCO, after consultation with the association of Drugs manufacturers, has issued manufacturing / marketing permission for Amphotericin B Liposomal Injection to eleven firms. Union Government is also importing the drug to fill the gap between the requirement and domestic production. Since this Amphotericin B Liposomal Injection is very much essential for the treatment of Mucormycosis, the Committee recommend that the Department of Pharmaceuticals should take necessary steps for augmenting the production of the drug in the country as per the requirements of the country. Progress made in this regard should be intimated to the Committee. Services of Ministry of External Affairs should also be utilized for the import of required quantum of the medicine to fill the gap between the domestic production and the requirement. Moreover, foolproof arrangements should be made for equitable and fair distribution of the drug to the States/UTs according to their requirements in case of allocation of the same by the Union Government.

RECOMMENDATION No-15

Provide Quality and Affordable Medical Oxygen in all States/UTs

The Committee note that the Government of India, along with the State Governments took all possible steps to tackle the unprecedented surge in oxygen demand that arose in the second wave of Covid-19. Further the Ministry of Health and Family Welfare closely monitored the availability and supply of Medical Oxygen and necessary infrastructure available with respective State/UTs for management of COVID-19 effectively. Liquid Medical Oxygen (LMO) supply, which was about 1,292 MTs per day in February 2021 increased to 9,690 MTs in May, 2021. On 28th May 2021, a total of 10,250 MTs of LMO was allocated to the states. This was done by enhancement of LMO production in steel plants as well as in other LMO plants. Moreover, Pressure Swing Adsorption (PSA) oxygen generation plants are being established in each district hospital, especially in far flung areas enabling the hospitals to become self-sufficient in generation of oxygen for their needs and thereby, reduce the burden on the medical oxygen supply grid across the country. As on 3rd August 2021, out of a total 1,222 allocated PSA plants, 283 have been commissioned. As LMO is imperative for saving lives of critical COVID 19 patients, the Committee recommend that the Union Government should continuously monitor the availability of LMO in each State and UT and should take all necessary steps to ensure the availability of the required quantum of LMO in each State/UT on day to day basis. Concrete steps should also be taken for the commissioning of all the 1222 PSA oxygen generation plants in all the States/UTs. State/UT-wise progress made in this regard should be intimated to the Committee.

RECOMMENDATION No-16

Price of Oxygen Concentrators

The Committee note that Oxygen Concentrator was under voluntarily registration regime w.e.f. 01.04.2020 and now under mandatory registration regime w.e.f. 01.10.2021. NPPA vide Gazette Notification dated 03.06.2021 has capped the Trade Margin for Oxygen Concentrators at 70% considering current PTD as base for a period of six months till November 2021. Subsequently, the downward revision in price up to of 54% has been reported in 70 products/brands, showing reduction in MRP up to Rs. 54,337 per unit. Further, 58 brands have reported price reduction up to 25% and 11 brands between 26-50%. Out of 252 products/brands reported, 18 products/brands reported by the domestic manufacturers did not show any decline in prices. As reported by NPPA the average price range of oxygen concentrators after Trade Margin Rationalisation notification of NPPA is Rs 29,468.00 to 2,47,533.00 for Portable 5LPM (Litres Per Minute) Oxygen Concentrator and Rs.59,000.00 to Rs 2,70,000.00 for Portable 10 LPM Oxygen Concentrator; for Stationary-5LPM it is Rs. 47,600.00 to Rs 1,73,240.00 and Rs 70,000.00 to Rs. 2,66,980.00 for Stationary 10 LPM Oxygen Concentrator. In this regard, the Committee feel that that the price range of the oxygen Concentrators is still on higher side even after Trade Margin Rationalisation (TMR) and that this continuously be an unaffordable medical device for the majority of the people in the country. The Committee, therefore, recommend that the Department of Pharmaceuticals and NPPA should consider capping of the prices of various types Oxygen Concentrators so as to make them affordable to common man. Department of Pharmaceuticals may also consider manufacture of Oxygen Concentrators by Pharma PSUs under it so that quality Oxygen Concentrators may be made available at affordable prices to the people of the country.

RECOMMENDATION No-17

Covering medical devices for COVID 19 treatment under National List of Essential Medicines

The Committee is informed that at the beginning of the COVID-19 pandemic in February 2020, India was dependent on high-end imported ventilators. To meet the need of States and Hospitals for ventilators, domestic production of ICU ventilators was encouraged. Based on the assessed requirement, orders for around 60,000 ventilators were placed for supply to State/ UTs. MoHFW has been supplying ventilators to the States/UTs based on the demand projected by the States/ UTs. The allocation to hospitals/ institutions within the States/ UTs is being made by them based on their assessed requirement in the hospitals, availability of required infrastructure in the hospitals, trained manpower to handle ventilators etc. As on 03.08.2021, MoHFW has supplied 49,246 ventilators to the States/ UTs. Further, the Department of Pharmaceuticals has also stated that ventilators have been notified by MoHFW as Drugs under Drugs & Cosmetic Act, 1940 w.e.f. 1st April 2020 and it is presently under voluntarily licensing regime of CDSCO for 42 months i.e. till September 2023. Ventilator is a non-scheduled Medical Device and under the DPCO-2013, manufacturer/importer of non-scheduled medical devices is at liberty to fix the maximum retail price launched by it, but cannot increase it by more than 10% during preceding 12 months. Further, an extensive online training programme has been launched by MoHFW on 21.05.2021 where the manufacturers of ventilators are providing online training to all the States/UTs. Till 05.08.2021, total 17,292 Doctors, Para-medical Personnel/ ICU Technicians/ Bio-Medical Engineers of States and UTs have got trained. Since the Ventilators are also covered under voluntary licensing regime under Drugs and Cosmetic Act, 1940 the Committee feel that all Medical Devices like Ventilators, Oxygen Concentrators etc should be kept under scheduled drugs category by the Department of Pharmaceuticals and NPPA so that these

medical devices can be made available to the people/hospitals at affordable prices till the pandemic is completely over. The Committee, therefore, recommend that all medical devices critical to COVID-19 treatment like Ventilators, Oxygen Concentrators etc. should be covered under National List of Essential Medicines for effective price control. Department of Pharmaceuticals can also consider manufacturing of ventilators by Pharma PSUs under it to make available quality Ventilators at competitive prices to the hospitals.

RECOMMENDATION No-18

Real time web platform on availability of COVID Medicines and Medical Devices

The Committee note that once the drugs are allocated and procured by the States/UTs Governments, actual utilisation of the drug is monitored at different administrative levels in respective State/UTs. Further, the Ministry of Health and Family Welfare is operating a COVID-19 portal in which all States can fill in and access real time information. COVID 19 INDIA PORTAL is a Real time web platform to analyze, understand and keep track on COVID pandemic situation across country. This portal is getting used by more than 20,000 users from various level such as National / State/ District. From the data fed in by the states a wide variety of reports are available to them to keep track of day to day utilization and availability of critical COVID medicines and medical devices at village, block, district, state and central level. These datasets help MoHFW in data based decision support. This portal is integrated with CV analytics portal, National Disaster Management Authority (NDMA), NIC data-hub, Arogyasetu, NCD, various State COVID19 portals. The Committee feel that it is important to further strengthen this real time web platform so that real time information regarding availability of critical COVID medicines and medical devices at village, block and district levels is available with the Department of Pharmaceuticals and Ministry of Health and Family Welfare to

enable them take immediate necessary action in case of shortage of medicines and medical devices at any level. The Committee, therefore, recommend that the Ministry of Health and Family Welfare and the Department of Pharmaceuticals should take concrete steps in coordination with the State Governments to ensure that the real time information is fed by the every district authority regarding block and village level availability of medicines and medical devices for the treatment of COVID 19 treatment. Necessary training for the operation of this real time web platform should be given to all the stakeholders involved in its operation. Progress made in this regard should be intimated to the Committee.

RECOMMENDATION No-19

Exemption of Basic Customs Duty and GST on medicines and medical devices for fighting COVID 19

The Committee note that Basic Customs Duty was exempted for various medicines and medical devices used for fighting COVID 19 during 2021. Further GST Council in its 44th Meeting decided to reduce the GST rates which were notified on 14th June, 2021. GST was reduced to 5% on most of the medicines, Oxygen, Oxygen generation equipment and related medical devices including ventilators, Testing Kits and Machines and Other Covid-19 related relief material such as pulse Oxymeters, hand sanitizers, temperature check equipments etc. Since the pandemic is creating wave after wave and the people of the country are under constant threat, the Committee feel that though the GST council has reduced the GST on COVID related medicines and medical devices, the need of the hour is to make these products more affordable to the people. Hence, the Committee strongly recommend that the Department of Pharmaceuticals in coordination with Ministry of Health and Family Welfare (MoHFW) should submit a proposal to GST Council to explore the possibility of exempting all the essential medicines and medical devices

including, Liquid Medical Oxygen, Oxygen Concentrators, ventilators, pulse oximeters, hand sanitizers, temperature check equipments, etc used for the treatment of COVID 19 from the purview of GST. Further Basic Customs Duty exemptions on various medicines and medical devices related to COVID 19 may also be continued till the pandemic is over. This recommendation of the Committee may be sent to the Ministry of Finance for taking appropriate action in this regard and furnish reply to the Committee at the earliest.

New Delhi;
16 March, 2022
25 Phalguna, 1943 (Saka)

KANIMOZHI KARUNANIDHI
Chairperson,
Standing Committee on
Chemicals and Fertilizers.

ANNEXURE-1

GUIDELINES FOR RATIONAL USE OF OXYGEN FOR MANAGEMENT OF COVID -19

The Ministry of Health and Family Welfare had issued an advisory on the rational use of oxygen vide D.O letter/1830290/immunization/2020 dated 25.09.2020. In the wake of rising cases of COVID-19 and an escalated need to ensure rational use of oxygen, a need was felt to review the advisory and issue updated comprehensive guidelines.

These guidelines are based on the recommendations of the leading clinical teams of the country who participated in a consultation as held on 22/04/2021, chaired by Dr. V.K. Paul, Member, NITI Aayog. Additionally, inputs of the Joint Monitoring Group (JMG) headed by Director General of Health Services (DGHS) MoHFW and Prof. (Dr.) Randeep Guleria, Director, AIIMS,New Delhi and Prof. (Dr.) Balram Bhargav, DG ICMR cum Secretary, Department of Health Research are included.

These guidelines aim **to promote judicious use of oxygen therapy in individual cases, and to enhance accountability for oxygen conservation through monitoring and audit without compromising quality of care.**

The majority of patients of COVID- 19 have mild illness. Out of 100 patients , 80 are treated at home or COVID care centres. Out of the remaining 20, about 17 have moderate disease needing oxygen beds. Only 3 are in ICUs and are treated with oxygen therapy by Non Rebreathing mask (NRBM), Non Invasive ventilation (NIV), High Flow Nasal Cannula (HFNC) , and Invasive ventilation.

Oxygen is a precious drug that should be used judiciously and the following action points are necessary to achieve this objective. These guidelines should be implemented by all the states and UTs.

RESPONSIBILITY OF THE HEALTH TEAM: Judicious use

1. The flow of oxygen should be adjusted to the lowest permissible level to target an oxygen saturation of 92%-94% for the hospitalized COVID 19 patients.

2. Indiscriminate use of BIPAP/HFNC should be avoided. When required, BIPAP should be preferred over HFNC; the latter consumes enormous amount of oxygen. HFNC device should be used only in the ICU setting under supervision of a respiratory physician/physician. Patient should be put on HFNC only after approval of the senior most respiratory physlcian/physician.

3. Prone positioning should be intermittently done in patients of COVID -19, along with adjunctive physiotherapy. This optimizes the respiratory status.

4. Individualization of oxygen therapy should be done taking into account the clinical signs like respiratory rate etc. and not just the saturation level. Once the desired

saturation is achieved, flow of oxygen should not be increased as it may not provide any additional benefit to the patient. Up-titration instead of down titration of oxygen flow levels should be the norm.

5. Triaging of patients as per their oxygen status should be done at regular intervals.

6. An audit of the oxygen use by the ICU / ward should be done by the clinical team leader on a daily basis.

RESPONSIBITIES OF STATE/HOSPITAL ADMINISTRATORS:

Monitoring and Audit

1. A team of one Nurse and one OT Technician may be designated as **Oxygen Monitoring Team** for each shift at each hospital/health facility level. The team will visit all areas where oxygen supply / therapy is instituted.

- Inspect the gas pipeline, wall mounted gas outlets, as well as gas cylinders to detect and promptly address leakages, if any. Nurse in the team will check the oxygen mask on a regular basis.
- Ensure closure of valves during 'no-use' at all times.
- Sensitize nurses and technlcians for conservation of oxygen.

2. At the facility level, an **Oxygen Audit Committee** may be formed in every hospital which may consist of Additional Medical Superintendent, Head of Anesthesia, Head of Respiratory Medicine (Head of Internal Medicine incase Respiratory Medicine department does not exist) and Nursing Superintendent.

3. The Oxygen Audit Committee will be mandated to supervise inventory planning, oxygen consumption pattern ,regular repair and maintenance of gas pipelines, gas plant, and wall mounted gas outlets etc. It should review the consumption pattern of oxygen twice a week and conduct and audit and reduce oxygen consumption if found to be in excess.

4. The hospital management should reduce all elective and emergency services to a minimum in view of the present pandemic situation

5. Regular training of OT Technicians and Nurse should be undertaken on proper oxygen administration and monitoring, and on conserving oxygen.

6. District Magistrate (DM) assisted by the Chief Medical Officer (CMO) of the district must also monitor the consumption including the rational use of oxygen in all facilities of the district on a weekly basis. Home oxygen cylinders should not be encouraged but the use of oxygen concentrators at home should be promoted whenever required.

ANNEXURE-2

Guidelines for Buffer Stock Management of COVID-19 Drugs

1. INTRODUCTION:

Drugs play a very crucial role in COVID-19 management. Access to drugs for COVID-19 patients proved to be a challenge during the 2'd surge of COVID- 19 in India. Certain categories of drugs were found to be in acute shortage in the for 3-4 weeks due to sudden surge in COVID-19 cases. There was huge gap between requirement and supply of a couple of drugs for COVID-19 and COVID-19 Associated Mucormycosis (Mucormycosis), and there were critical issues of non-availability of the drugs and accessibility to the patients.

Government undertook various measures for augmenting the supplies of these drugs during the 2nd surge of COVID-19 by encouraging domestic manufacturers to augment production of the drugs, putting in place coordination mechanism with manufacturers/ States and allocating quantities of drugs to States/ UTs depending upon their respective case load, procuring through import of drugs from other countries and advising States/UTs on the rational use of these drugs.

Indian Pharmaceutical Industry is capable of manufacturing large quantities of quality Active Pharmaceutical Ingredients (API) and Formulations used in the treatment of COVID-19. However, required quantities of certain drugs could not be made available timely during the 2^{n}d surge of COVID-19 cases, mainly on account of sudden increase in demand, long lead time to manufacture API and formulations (Injections), non-availability of APIs and shortage of certain excipients, mainly imported items and packing materials.

Industry may not be able to manufacture and keep sufficient stocks of these medicines since maintaining such a large inventory in anticipation of demand may not be economically viable. Even during the 2nd surge of COVID-19 cases, Industry needed the support of the Government in the form of advance payments for making necessary investments and augmenting the production of drugs specifically used for COVID-19.

In order to ensure continuous supply of drugs for treatment of COVID-19 cases and drugs required for management of sequel of COVID-19 such as Mucormycosis and Multisystem Inflammatory Syndrome in Children (MIS-C) during any future surge, definitive need has been felt to keep buffer stock of these drugs by both Central and State Governments. The main objectives of keeping buffer stock are:

To expand and enhance capabilities to respond any unforeseen emerging situation.

- To ensure continuous supply in case of any sudden surge.
- To guard against high cost procurements during emergency situation.
- To prevent manufacturing of spurious drugs.
- To minimize the risk of hoarding.
- To prevent black-marketing and panic buying by the public.
- To build trust and confidence among the public.
- To undertake equitable distribution across the country and in states.

In view of the above it is extremely essential to keep buffer stock of certain drugs for use in any possible future surge of COVID-19 cases.

2. Identification of drugs for buffer stock:

Various therapeutic categories of drugs are used in the treatment of COVID- 19 and COVID-19 associated diseases. While certain drugs are used only for the treatment of COVID-19, others are repurposed for treatment of COVID-19. There are some other drugs which are used for treating COVID-19 associated symptoms/complications, like Paracetamol Tablets, anticoagulants, etc. In addition, there are drugs which are used specifically for the treatment of COVID-19 associated diseases e.g. Mucormycosis.

Clinical Management Protocol or Clinical Guidance for Management of Covid- 19 Patients by the Joint National Task Force for COVID-19 prescribes drugs for treatment and management of COVID-19/ COVID Associated Mucormycosis. There are certain other drugs which have been approved by Central Drugs Standard Control Organisation, the Central Drug Regulator for restricted use under emergency situation for the treatment of COVID-19 based on recommendations of Subject Expert Committee but not included in the clinical management protocol.

Drugs specified in the Management Guidelines, as well as certain non-protocol drugs have been seen to be extensively used for the treatment of COVID-19 cases. Therefore, looking at the experience gained during the 2nd surge of COVID-19, there is a need to maintain buffer stock of certain drugs, apart from closely monitoring on the availability of other drugs for COVID-19.

The drugs for which buffer stock is required to be maintained may be considered based on following aspects:

- Drugs which need long lead time to manufacture formulation.
- Drugs prescribed for moderate and severe cases.
- Drugs which were widely prescribed during second COVID-19 surge
- Drugs included in Clinical Management Guidance.
- Drugs for which no indigenous manufacturing, and are only imported.
- Drugs which are single sourced.

- Drugs which are limited supply per month.
- Drugs having minimum 24 months shelf life.

However, the above assumptions may change depending upon the situation. COVID-19 scenario is continuously evolving, and accordingly new scenarios/ guidelines/ protocols may emerge, which can necessitate changes in both the assumptions and the drugs decided to be buffer stocked.

3. Drugs for buffer stock management:

Based on criteria/ assumptions mentioned above, current set of guidelines, and experience of shortfall/ likely shortfall on account of their extensive use during the 2nd Wave, a suggestive list of drugs to be a part of the buffer stock has been identified. This list includes the following drugs -

a. For COVID-19 treatment

1. Enoxaparin Injection 40 mg
2. Methyl Prednisolone Injection 40 mg/ml
3. Dexamethasone Injection 4 mg/ml
4. Remdesivir Injection 100 mg per vial
5. Tocilizumab Injection 400 mg

b. For treatment of Mucormycosis

6. Amphoterecin B Deoxycholate Injection 50 mg per vial
7. Posaconazole Injection 300 mg per vial

c. For treatment of MIS-C

8. Intravenous Immunoglobulin (IVIG) 2G/Kg
9. Methyl Prednisolone Injection 40 mg/ml (Also used for COVID)
10. Dexamethasone Injection 4 mg/ml (Also used for COVID)

This list is a dynamic and is only indicative. The States/UTs may suitably customise the list in accordance with their local needs and requirements for treatment/ management of COVID-19 and its sequelae such as CAM and MIS- c.

3.2 There are a few drugs in the above list which can be interchangeably used as they have similar therapeutic action. For estimating quantities of such drugs for buffer stock, ratio of consumption of drugs during 2nd wave of COVID-19 surge has been taken into consideration. Accordingly, quantities of Methyl Prednisolone and Dexamethasone for buffer stock has been considered to be in the ratio of 10:90, whereas Amphotericin-B Deoxycholate and Posaconazole in the ratio of 75:25.

4. Estimation of quantities to be maintained for Buffer Stock for drugs:

It is very difficult to predict likely number of COVID-19 cases in the coming days/ months, considering the evolving nature of pandemic, and, therefore, the quantities of drugs required to be stocked are also difficult to be forecasted. However, the data available for the trajectory and extent of COVID cases during the second surge, and the valuable experience gained in successfully combating the recent surge in COVID cases, does provide valuable insights for identification of drugs for which the buffer stock needs to be maintained. The experience gained so far, also provides the relevant insights on estimation of buffer stock requirements and indicates that such estimation will have to factor-in the following parameters —

1. The trend of daily new COVID cases during the surge period.
2. The peak number of cases observed during the surge and the peak number of cases for which the government may like to prepare.
3. The distribution of COVID cases in terms of severity of infection, i.e. the proportion of mild, moderate and severe cases.
4. The prevailing technical treatment and management protocols for mild, moderate and severe cases of COVID-19, specifying the drugs and treatment regimen in terms of period of treatment and dosages.

It may be noted that except for Remdesivir, which is exclusively used for management of COVID-19 cases, all other identified drugs are usually used for other medical conditions. Hence, the usual production and sales of drugs should not be assumed to be available for management of COVID-19, as these would also be required for management of medical conditions for which these medicines are usually used.

All of the drugs except IVIG (for MIS-C) for which the lead time for production is 2 months, have a lead time of 15 to 30 days. Therefore, while estimating the requirements for various drugs, the best possible estimates for likely number of new COVID-19 cases in a 30 day period from the start of surge, must be drawn.

The total quantity worked out on the basis of afore-mentioned criteria and assumptions would include the drugs required both for public and private sector hospitals/ medical care institutions. The public sector is expected to cater to around 60% of the total patient load. However, a flexible approach has to be adopted and the estimates may need to revised based on the trend, trajectory and extent of new cases, wherever necessary.

A suggestive process and an example for estimation is given in Annexure - A.

5. Roles and Responsibilities:

5.1 In order to ensure continuous availability of drugs during any possible next surge, there is a need to procure and maintain buffer stock of COVID-19 drugs (Drugs as stated under Clause 3.1).

5.2 State/ UT Governments shall be responsible to ensure continuous supply of drugs in any future surge of COVID cases. All measures should be taken by them to make available drugs to all patients in such a situation.

5.3 The States must initiate procurements on priority for building up buffer stocks. The buffer stocks should substantially be in place by 31 t of July, 2021.

5.4 States shall, in addition, work closely with the private hospitals/ institutions within their respective jurisdiction, in order to ensure that they also create adequate stock of buffers for addressing their likely patient load.

5.5 The central government shall also make an assessment of buffer stocks required. The Central Government too shall procure and maintain a reasonable percentage of the total requirement to address any possible variations in geographical spread and the extent of COVID-19 across States, to supplement supplies to states/UTs wherever so necessary in view of such variations. The Central Government shall also mobilize resources for the stock that it shall maintain.

5.6 The Central Government may, on the request of the respective State/ UT, facilitate procurement of buffer stocks for North Eastern states and UTs. However, the states/ UTs shall be responsible for maintenance of such buffer stocks.

5.7 As a part of emergency preparedness, Governments shall engage with the manufacturers, distributors, suppliers and sellers of COVID-19 drugs. State Governments may also work with the manufacturers for maintaining inventories of sufficient quantities of these drugs.

Annexure - A

Process of estimation of requirement of buffer stock quantities

Example - Estimation of requirements of Remdesivir

1. A suggestive process for estimation of requirements of buffer stock of Remdesivir is presented herein. The second surge in COVID cases lasted for 75 days from 1st April to 15th June 2021. It is assumed for purposes of this estimation that the next surge will be of the same duration and shall have the same distribution. The stocks for the above case load for at least 30 days has been recommended. Reason for keeping stock for 30 days is based on lead time required to manufacture these drugs.

2. Following parameters are used/worked out for estimation —

a. The peak number of new cases is estimated at 1.5 times the peak of the second surge (4.14 lakh new cases on 7th May 2021) at 6.21 lakh cases.

b. Daily average number of cases reported on ICMR's portal from 1 t April to 15'h June, 2021 (the duration of 2nd wave), of the 2nd wave of COVID-19 is calculated. This works out to 2.29 lakh new cases per day which is 55 % of the peak number of cases i.e. 4.14 lakh on 7th May, 2021.

c. The average number of cases, using 6.21 lakh peak cases as a bench mark, works out to 3.43 lakh cases per day (55% of the peak number of cases) assuming the surge lasts for 75 days and with similar spread of cases as during the 2'd wave.

d. Total number of cases for 30 days (with average of 3.43 lakh cases per day) will be 1.029 crore. For the purpose of buffer stock, the figure may be rounded to 1.0 crore new cases.

e As per the prevailing technical guidelines it is estimated that 23o/ of total cases would require hospital admissions or in-patient care, with 3% on ICU beds, 15% on non-ICU but oxygen (O2) supported beds and rest 5% on non-ICU and non-02supported beds.

f. Remdesivir is recommended under the technical guidelines for management of such cases that may require in-patient care on ICU beds

or on non-ICU but oxygen (O2) supported beds. This amounts to 18% of total cases, i.e. 18 lakh cases.

g. 60% of the patients would seek care in government hospitals. Therefore, the buffer stock quantity for Remdesivir works out to (18 x 0.6) = 10.80 lakh patient courses.

h. This includes the requirements for both the central and state government institutions. The requirement as worked out in patient courses can be converted to vials/tablets as per the technical guidelines for management of COVID cases and for COVID Associated Mucormycosis (CAM) and Multi-Infection Syndrome in Children (MIS-C).

3. Quantities may vary from drug to drug based on its dosage & frequency of administration, and percentage of patients requiring the drug. Based on the inputs on Clinical Management Guidelines by National task Force and JMG of DGHS (dated 19.05.21), percentage of patients requiring these medicines is as follows:

S.N0	Name of the drug	°/« of Total COVID-19 cases
1	Enoxaparin Injection	23 %
2	Methyl Prednisolone Injection	23 %
3	Dexamethasone Injection	23 %
4	Remdesivir Injection	18 %
5	Tocilizumab Injection	40% of 3º/
6	Amphotericin B Deoxycholate	1% of 23°/
7	Posaconazole Injection	1% of 23%
8	IVIG Injection	5º/oof 5% of 12% *

*(12% is the observed number of paediatric cases out of Total COVID-19 cases, 5% is the percentage of severe/Moderate cases within the paediatric category, and 5% is the percentage of such severe/ moderate cases requiring IVIG injection).

ANNEXURE-3

Advisory for Rational use of Remdesivir for COVID-19 Treatment

The purpose of this document is to stop to irrational use/ over prescription of this reserve/ experimental/ emergency use authorisation drug Remdesivir. For this reason, Joint Monitoring Group under Chairmanship of DGHS took into consideration findings of thefollowing studies to issue this advisory:

A. The 'Adaptive Covid – 19 Treatment [GM1] Trial' found that Remdesivir is useful in cases of Covid – 19 with SpO2 ≤ 94% on room air (moderate to severe cases) if it is administered within 7 to 10 days of illness. Remdesivir led to a shorter median time from randomization to recovery (10 days, vs. 15 days with placebo) and may have reduced the time to hospital discharge (12 days vs. 17 days) but did not show a mortality benefit.[1]
B. The 'Solidarity Trial' conducted by WHO in 30 countries from March 2020 at 405 hospitals; 11330 adults underwent randomization; 2750 were assigned to receive Remdesivir. The interim results of the 'WHO Solidarity trial' published on December .2020 showed that Remdesivir had little or no effect on hospitalized patients with COVID-19, as indicated by overall mortality, initiation of ventilation, and duration of hospital stay.[2]

In view of the above:

1. Remdesivir is to be used only in select moderate/ severe hospitalised Covid - 19 patients on supplemental oxygen as **it is a reserve drug approved under Emergency Use Authorization** only based on limited scientific evidenceglobally.
2. It is not indicated in mild Covid – 19 patients who are in home care/ Covid Care Centres.
3. Physicians/ Doctors are advised to exercise extreme caution in using this reserve/ experimental/ emergency use authorisation drug Remdesivir to stop it's misuse as this is only an experimental drug with potential to harm, has relatively high cost and has limited availability.

Further, following additional steps are recommended to stop misuse of Remdesivir:

- Remdesivir must be advised by senior faculty members/ specialists directly involved in patient's care.
- If Remdesivir has to be advised/ ordered during odd hours, it should be done by the duty doctor after telephonic consultation with a senior faculty member/ specialist/ unit in - charge.
- Advise/ order for Remdesivir must be written and bear the name, signature and stamp of the concerned doctor.
- **Every hospital needs to set up Special Drug Committee (SDC)** which must review use of Remdesivir in their hospital periodically. It would be preferable to have a Pharmacology Professor/ faculty as a member of the SDC wherever

available.

- The Special Drug Committee should share their findings with the clinicians periodicallyto ensure rational and judicious use of Remdesivir.
- Remdesivir should be procured and provided by the hospitals only; the patient's attendants/ relatives should not be asked to procure Remdesivir from retail market.

ANNEXURE-4

Advisory for rational use of Steroids and Tocilizumab in the treatment of Covid - 19 patients

The purpose of this document is to stop the irrational use/ over use of Steroids and Tocilizumab (experimental/ off – label drug). For this reason, Joint Monitoring Group under the Chairmanship of DGHS took into account the following facts:

Steroids:

In the most recent guidelines published by the Infectious Diseases Society of America (IDSA), updated on 14th April 2021, steroids were strongly recommended for treatment of hospitalized moderately severe and critically ill* Covid 19 cases.[1]

Steroids are indicated for treatment of moderate and critically ill hospitalized cases.

Recommended dose: Dexamethasone 6 mg IV or per oral for 10 days (or until discharge) or equivalent glucocorticoid dose may be substituted if dexamethasone is unavailable: by Methylprednisolone 32 mg (per oral or IV) or 50 mg hydrocortisone intravenously every 8 hours or Prednisone 40 mg (per oral).

Evidence from observational studies suggests that steroids prolong viral shedding, and that use of high- dose steroids is associated with increased mortality as compared to low-dose steroids in patients with severe COVID-19. Use of steroids even for short duration (less than 14 days) is associated with increased incidence of complications such as Hyperglycaemia, GI bleeding, sepsis, heart failure as well as risk of reactivation of latent infections like Hepatitis B Virus, Herpes Simplex Virus and Tuberculosis.

Therefore, steroid are not indicated and may be harmful in mild and asymptomatic cases (with SpO_2 > 93% and not requiring supplemental oxygen).[2]

In view of the above, Physicians/ Doctors are advised to exercise **extreme caution** in using Steroids on Covid – 19 patients to curtail it's overuse/ irrational use.

Inhalational Budesonide:

An open-label, parallel-group, phase 2, randomised controlled trial (Steroids in Covid - 19; STOIC) of inhaled budesonide, compared with usual care, in adults within 7 days of the onset of mild COVID-19 symptoms, demonstrated that early administration of inhalational Budesonide in the dose of 2 puffs of 400 µg twice daily reduced the likelihood of need for urgent medical care and also reduced time to recovery (low quality of evidence).

Use of inhalational budesonide is conditionally recommended in the dose of 1600 µg / day (400 µg/ 2 puffs twice daily) in patients having mild disease(oxygen saturation more than 93%) and persistent cough.

Tocilizumab

This has been advised by joint team of AIIMS, ICMR and JMG as an off – label drug for use only in severeand critically ill patients of Covid – 19.

Tocilizumab is an immunosuppressant. It's use is indicated in severe Covid – 19 disease, if the patient is not improving despite administration of Steroids, and has significantly raised inflammatory markers (C Reactive Protein≥75 mg/L).[1]. It may be used after 72 hours of using steroids if patient does not show any improvement and requires increasing ventilatory support to maintain SpO_2 > 92%. However, care should be taken by the treating physician/ intensivist to ensure that the patient is not having any bacterial/ fungal/ tubercular infection at the time of administration of tocilizumab.

Dosage: single dose of 8 mg/kg body weight (not more than 800 mg) in 100 ml normal saline over one hour.

In view of the above, Physicians/ Intensivists are advised to exercise extreme caution while usingTocilizumab to prevent it's overuse/ irrational use.

ANNEXURE-5

Guideline for management of Mucormycosis in Covid – 19 patients

Background:

There are reports that there has been a significant increase in in number of cases of Mucormycosis in Covid – 19 patients during treatment in hospitals and after discharge in different parts of the country.

Scope of this document:

The scope of this document is to provide a guidance to clinicians (physicians/ respiratory physicians/ intensivists/ ENT surgeons etc.) to detect Mucormycosis at an early stage in patients who are hospitalised for treatment of Covid – 19 (as well as those discharged after treatment) and treat such patients optimally.

Time of presentation: variable but usually around 3rd week of onset of symptoms of Covid – 19.

Reasons for increase in mucormycosis in Covid – 19 patients:

1. Hyperglycemia due to uncontrolled pre-existing diabetes and high prevalence rates of mucormycosis in India per se.
2. Rampant overuse and irrational use of steroids in management of Covid – 19.
3. New onset diabetes due to steroid overuse or severe cases of Covid – 19 per se.
4. Prolonged ICU stay and irrational use of broad spectrum antibiotics
5. Pre-existing co-morbidities such as hematological malignancies, use of immune suppressants, solid organ transplant etc.
6. Breakthrough infections in patients on Voriconazole (anti – fungal drug) prophylaxis.

Signs and symptoms:

1. Facial pain, pain over sinuses, pain in teeth and gums
2. Paraesthesia / decreased sensation over half of face.
3. Blackish discolouration of skin over nasolabial groove/ alae nasii.
4. Nasal crusting and nasal discharge which could be blackish or blood tinged.
5. Conjunctival injection or chemosis.
6. Periorbital swelling.
7. Blurring of vision/ diplopia.
8. Loosening of teeth/ discoloration of palate/ gangrenous inferior turbinates.
9. Worsening of respiratory symptoms, hemoptysis, chest pain, alteration of consciousness,headache.

Investigation:

i. NCCT PNS (to see bony erosion).
ii. HRCT chest (≥ 10 nodules, reverse halo sign, CT bronchus sign etc.) and CT Angiography.
iii. MRI brain for better delineation of CNS involvement.

Diagnosis:

i. KOH staining and microscopy, histopathology of debrided tissue and culture
ii. MALDI-TOF if available
iii. Presence of Ribbon like aseptate hyphae 5-15 µ that branch at right angles.

Treatment:

- One should have a high index of suspicion of invasive fungal infection such as Mucormycosis in the presence of predisposing conditions as mentioned above. Timely initiation of treatment reduces mortality. Multidisciplinary Team approach is required. Treatment of Mucormycosis involves combination of surgical debridement and antifungal therapy.
- Liposomal Amphotericin B in initial dose of 5mg/kg body weight (10 mg/kg body wt in case of CNS involvement) is the treatment of choice. Each vial contains 50 mg. It should be diluted in 5% or 10% dextrose, it is incompatible with normal saline/ Ringer Lactate.. It has to be continued till a favourable response is achieved and disease is stabilized which may take several weeks following which step down to oral Posaconazole (300 mg delayed release tablets twice a day for 1 day followed by 300 mg daily) or Isavuconazole (200 mg 1 tablet 3 times daily for 2 days followed by 200 mg daily) can be done.
- The therapy has to be continued until clinical resolution of signs and symptoms of infection as well as resolution of radiological signs of active disease and elimination of predisposing risk factors such as hyperglycemia, immunosuppression etc, it may have to be given for quitelong periods of time.
- Conventional Amphotericin B (deoxy cholate) in the dose 1-1.5mg/kg may be used if liposomal form is not available and renal functions and serum electrolytes are within normal limits.

Control of Blood glucose:

Refer to MoHFW guidelines for screening and management of hyperglycemia in Covid

- 19available on website of MoHFW:

https://www.mohfw.gov.in/pdf/ClinicalGuidanceonDiabetesManagementatCOVID19Patient Managem entFacility.pdf

Do's for Doctors:

- Use steroids judiciously- correct evidence based dose, right timing and for recommendedduration.
- Rational use of antibiotics.
- Timely initiation of Amphotericin B therapy.
- Strict monitoring as well as control of blood glucose in admitted as well as post dischargepatients.
- Use Insulin in patients with Diabetes Mellitus who are admitted for Covid – 19 treatment.
- Keep high index of suspicion in presence of risk factors, daily examination of eyes, nose andmouth for detecting signs

- Use clean sterile water for humidifiers

Don'ts for Doctors:

- Don't miss the early warning symptoms and signs.
- Blocked nose doesn't always means bacterial sinusitis, don't forget Mucormycosis.
- Don't lose crucial time, you may have to initiate therapy in relevant cases even beforediagnosis is made.

Do's for Covid – 19 patients:

- Keep the doctor informed about all your co - morbidities such as diabetes, hypertension,heart disease, any malignancy etc.
- Tell the doctor about all medicines being taken especially if under medication with immuno –suppressant drugs for any immune related disorder/ disease.
- Use masks and maintain personal hygiene.
- Immediately inform the doctor if you develop blocked nose with nasal discharge, unilateral facial pain/ numbness, any eye swelling, difficulty in vision, any discoloration around eyes,nose or mouth

Don'ts for Covid – 19 patients:

- Don't self medicate, especially don't take steroids on your own

Don't ignore warning signs detailed above.

ANNEXURE-6

Allocation and supply of Remdesivir, Tocilizumab and Amphotericin B

Allocation and supply of Remdesivir is as under:

S N	Name of State/UT	Total Allocation till 23.05.2021	Total Supply as on 12.09.2021
1	Andaman and Nicobar Islands	4000	3300
2	Andhra Pradesh	541000	814526
3	Arunachal Pradesh	6000	4946
4	Assam	102000	133032
5	Bihar	239000	164300
6	Chandigarh	22500	25510
7	Chhattisgarh	325000	229506
8	Dadra and Nagar Haveli and Daman and Diu	5000	3368
9	Delhi	310000	311955
10	Goa	64000	44093
11	Gujarat	575000	934591
12	Haryana	273000	309469
13	Himachal Pradesh	70000	42250
14	Jammu and Kashmir	118000	74957
15	Jharkhand	124000	182217
16	Karnataka	1425000	1019492
17	Kerala	375000	252590
18	Ladakh	5500	1500
19	Lakshadweep	4500	500
20	Madhya Pradesh	375000	399513
21	Maharashtra	1766000	2087024
22	Manipur	11500	34056
23	Meghalaya	10000	18350
24	Mizoram	6000	7598
25	Nagaland	8500	1006
26	Odisha	218000	280999
27	Puducherry	37000	23444
28	Punjab	196000	198802
29	Rajasthan	478000	414095
30	Sikkim	7500	4380
31	Tamil Nadu	560000	1179051
32	Telangana	247000	514022
33	Tripura	10000	5550
34	Uttarakhand	173000	103370
35	Uttar Pradesh	708000	542468
36	West Bengal	350000	245559
37	Central Govt. Institutions	104000	42274
38	Central Institutions other than under MoHFW	33000	1682
Total		**9887000**	**10655345**

Allocation and supply of Tocilizumab is as under:

Tocilizumab	Allocation date	Total allocation (Noof vials)	Supply as on 12th September, 2021
400 mg vial	30th April 2021 to States	9,900	9,606
	4th May 2021 to Central Govt Institutions		
	5th May 2021 to UTs		
80 mg vial	11th May 2021 to States/UTs andCentral Health Institutions	74,000	63,199
	7th June 2021 to States/UTs and CentralHealth Institutions		
	26th July 2021 to States/UTs andCentral Health Institutions		

SL No	State	Total Allocation of400 mg	Cumulative Supplies of 400 mgtill 12.09.2021	Total Allocation of80 mg vials	Cumulative Supplies of 80mgtill 12.09.2021
1	Andaman and Nicobar Islands	30	30	30	0
2	Andhra Pradesh	280	281	3845	2055
3	Arunachal Pradesh	30	0	145	0
4	Assam	50	30	1310	1220
5	Bihar	270	285	1255	1140
6	Chandigarh	50	50	105	105
7	Chhattisgarh	340	292	1505	141
8	Dadra and Nagar Haveli and Damanand Diu	50	50	30	30
9	Delhi	500	572	1015	1003
10	Goa	50	50	475	350
11	Gujarat	370	380	1705	1690
12	Haryana	240	240	1355	1355
13	Himachal Pradesh	45	45	495	105
14	Jammu and Kashmir	60	60	855	810
15	Jharkhand	145	145	700	625

16	Karnataka	855	848	9625	9615
17	Kerala	705	550	10015	10827
18	Ladakh	30	30	35	0
19	Lakshadweep	30	0	30	0
20	Madhya Pradesh	275	275	1320	1200
21	Maharashtra	1960	1975	11730	11134
22	Manipur	30	0	320	320
23	Meghalaya	30	30	185	35
24	Mizoram	30	30	170	0
25	Nagaland	30	0	95	58
26	Odisha	135	147	2145	2150
27	Puducherry	25	25	270	0
28	Punjab	200	318	1100	1122
29	Rajasthan	440	440	2445	2453
30	Sikkim	30	0	115	0
31	Tamil Nadu	315	427	5075	5205
32	Telangana	210	228	1190	1078
33	Tripura	30	30	390	200
34	Uttarakhand	125	125	2655	1363
35	Uttar Pradesh	870	820	1050	500
36	West Bengal	285	317	2215	2229
	Sub-Total	9150	9125	67000	60118
37	Central Institutions	750	481	7000	3081
Total		**9900**	**9606**	**74000**	**63199**

Allocation and supply of Liposomal Amphotericin-B is as under:

Sr. No.	State/UT	Total Allocation	Supply as on 12.09.2021
1	A&N Islands	0	0
2	Andhra Pradesh	119930	105535
3	Arunachal Pradesh	0	0
4	Assam	450	400
5	Bihar	12510	12830
6	Chandigarh	5000	9500
7	Chhattisgarh	8910	6490
8	D&D & D&N	500	500
9	Delhi	49880	56397
10	Goa	1370	1370
11	Gujarat	239900	203660
12	Haryana	60680	48808
13	Himachal Pradesh	980	220
14	J&K(UT)	1550	3290
15	Jharkhand	5670	4260
16	Karnataka	142530	85244
17	Kerala	5390	15370
18	Ladakh (UT)	0	0
19	Lakshdweep	0	0
20	Madhya Pradesh	89526	67401
21	Maharashtra	270945	210500
22	Manipur	350	200
23	Meghalaya	0	0
24	Mizoram	0	30
25	Nagaland	300	0
26	Odisha	3310	3310
27	Puducherry	760	730
28	Punjab	19870	21825
29	Rajasthan	138970	137058
30	Sikkim	0	0
31	Tamil Nadu	114940	109070
32	Telangana	124340	86305
33	Tripura	350	150
34	Uttar Pradesh	95580	95998
35	Uttarakhand	5940	6550
36	West Bengal	10970	5085
37	Central Institutions	76890	87262
Total		**1608291**	**1385348**

ANNEXURE-VII

MINUTES OF THE SEVENTH SITTING OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS

(2020-21)

The Committee sat on Tuesday, the 29th June, 2021 from 1545 hrs. to 1715 hrs. in Committee Room 'D', Parliament House Annexe, New Delhi.

PRESENT

Smt. Kanimozhi Karunanidhi- Chairperson

MEMBERS

LOK SABHA

2 Shri Ramesh Chandappa Jigajinagi

3 Shri Kripanath Mallah

4 Shri Satyadev Pachauri

5 Dr. M.K.Vishnu Prasad

6 Shri Arun Kumar Sagar

7 Shri Er. Bishweswar Tudu

8 Shri Prabhubhai Nagarbhai Vasava

RAJYA SABHA

9 Shri G.C.Chandrashekhar

10 Dr. Anil Jain

11 Shri Ahmad Ashfaque Karim

12 Shri M.V. Shreyams Kumar

13 Shri Jaiprakash Nishad

14 Shri Anthiyur P. Selvarasu

15 Shri Arun Singh

SECRETARIAT

1.	Shri Manoj K. Arora	-	Officer on Special Duty (LSS)
2.	Shri N.K. Jha	-	Director (CF&GP)
3.	Shri C. Kalyanasundaram	-	Additional Director (CF & MPL)
4.	Shri Panna Lal	-	Under Secretary

LIST OF WITNESSES

I. MINISTRY OF CHEMICALS AND FERTILIZERS

(DEPARTMENT OF PHARMACEUTICALS)

1.	Ms. S. Aparna	Secretary
2.	Shri Navdeep Rinwa	Joint Secretary
3.	Shri Rajneesh Tingle	Joint Secretary

II. REPRESENTATIVES OF NPPA

1.	Ms. Shubra Singh	Chairperson, NPPA
2.	Dr. Vinod Kotwal	Member Secretary, NPPA

III *REPRESENTATIVES OF OTHER MININSTRY*

1.	Dr. Mandeep Bhandari	Joint Secretary, Department of Health and Family Welfare
2.	Dr. M.K. Agrarwal	Additional Commissioner, Immunization Division Department of Health and Family Welfare.
3.	Shri A.K. Pradhan	Dy. Drugs Controller (India), CDSCO

2. At the outset, Hon'ble Chairperson welcomed the Members of the Committee and representatives of the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals) and other officials to the sitting. Their attention was invited to the provisions contained in Direction 55(1) of the Directions by the Speaker regarding confidentiality of the Committee's proceedings.

3. After the witnesses introduced themselves, Secretary of the Department of Pharmaceuticals briefed the Committee on the subject "Availability of Medicines and Medical devices for COVID management" through power point presentation.

4. Power point presentation was followed by discussion on several aspects of the

subject “Availability of Medicines and Medical devices for COVID management” The Hon'ble Chairperson and Members of the Committee raised queries on issues concerning the subject such as:-

(i) Status of availability of medicines like Remdesivir, Tocilizumab, Amphotericin-B and medical devices like medical grade oxygen, N-95 mask, ventilators etc.;

(ii) Need for Mechanism to visualize day to day usage and availability of critical medicines;

(iii) Reasons for low allocation of medicines to states with high Covid cases and suggested course correction in future;

(iv) Preparedness of the Department with respect to third wave which may affect children and measures to regulate the prices, demarcating the manufacturers and creation of a buffer stock of such medicines;

(v) Need to make Drugs Coordination Committee (DCC) a permanent body for continuous inter departmental coordination;

(vi) Need to review the Clinical Treatment Protocol for covid in view of inclusion of drugs like Remdesivir which do not prove to be life saving drugs;

(vii) Measures to ensure the dissemination of information regarding availability of medicines to the families of critically ill covid patients;

(viii) Status of import of Active Pharmaceutical Ingredients (API) required to manufacture medicines listed in the Clinical Treatment Protocol; and

(ix) Steps to control rising number of black fungus cases among covid patients in the country;

(x) Need for training technicians who operate ventilators and lack of availability of medical grade oxygen at village and block level.

5. The Secretary, Department of Pharmaceuticals and other officials responded to the aforesaid issues raised by the Committee.

6. The Chairperson thanked the witnesses for appearing before the Committee as well as for furnishing valuable information to the Committee. They were also asked to provide written replies to questions asked by the Members during discussion.

7 A copy of the verbatim record of the proceedings of the sitting has been kept.

The Committee then adjourned.

ANNEXURE-VIII

STANDING COMMITTEE ON CHEMICALS & FERTILIZERS
(2021-22)

Minutes of the Sixth Sitting of the Committee

The Committee sat on Wednesday, the 16th March, 2022 from 1500 hrs. to 1545 hrs. in Committee Room 'C', Parliament House Annexe, New Delhi.

PRESENT

SHRI ARUN SINGH- Chairperson (Acting)

MEMBERS

LOK SABHA

2. Shri Ramakant Bhargava
3. Shri Rajeshbhai Naranbhai Chudasama
4. Shri Ramesh Chandappa Jigajinagi
5. Shri Satyadev Pachauri
6. Smt Aparupa Poddar (Afrin Ali)
7. Dr. M.K.Vishnu Prasad
8. Dr. Sanjeev Kumar Singari
9. Shri Uday Pratap Singh
10. Shri Indra Hang Subba

RAJYA SABHA

11. Shri Ayodhya Rami Reddy Alla
12. Shri G.C.Chandrashekhar
13. Shri Jaiprakash Nishad
14. Shri Vijay Pal Singh Tomar
15. Shri K. Vanlalvena

SECRETARIAT

1. Shri Vinod Kumar Tripathi - Joint Secretary
2. Shri Nabin Kumar Jha - Director
3. Shri C. Kalyanasundaram - Additional Director
4. Shri Kulvinder Singh - Deputy Secretary
5. Shri Panna Lal - Under Secretary

2. Since the Chairperson of the Committee was unable to attend the sitting, the Committee chose Shri Arun Singh, MP to act as Chairperson for the sitting under Rule 258(3) of Rules of Procedure and Conduct of Business in Lok Sabha.

3. Thereafter the acting Chairperson welcomed the Members of the Committee to the sitting which was convened to consider and adopt four draft Reports. The Committee, then, took up for consideration and adoption of the following draft Reports:

(i) Availability of Medicines and Medical Devices for COVID Management (Department of Pharmaceuticals);

(ii) **xxx** **xxx** **xxx**

(ii) **xxx** **xxx** **xxx**

(iii) **xxx** **xxx** **xxx**

4. The Committee considered and adopted the Reports unanimously without any amendment.

5. The Committee then authorized the Chairperson to finalise the Reports and present them during the current session of the Parliament.

The Committee then adjourned.