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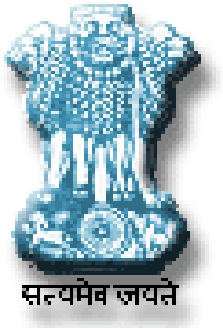
STANDING COMMITTEE ON CHEMICALS & FERTILIZERS
(2021-22)

(SEVENTEENTH LOK SABHA)

MINISTRY OF CHEMICALS AND FERTILIZERS
(DEPARTMENT OF PHARMACEUTICALS)

Action Taken by the Government on the Observations/Recommendations of the Committee contained in their Thirty-First Report (Seventeenth Lok Sabha) on 'Availability of Medicines & Medical devices for COVID Management' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)

THIRTY-FIFTH REPORT



LOK SABHA SECRETARIAT

NEW DELHI

August, 2022/ Sravana, 1944 (Saka)

CC&F No. 163

THIRTY-FIFTH REPORT

STANDING COMMITTEE ON CHEMICALS & FERTILIZERS

(2021-22)

(SEVENTEENTH LOK SABHA)

MINISTRY OF CHEMICALS AND FERTILIZERS
(DEPARTMENT OF PHARMACEUTICALS)

Action Taken by the Government on the Observations/Recommendations contained in their Thirty First Report of the Standing Committee on Chemicals & Fertilizers (Seventeenth Lok Sabha) on 'Availability of Medicines & Medical devices for COVID Management' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)

Presented to Lok Sabha on 08 August, 2022

Laid in Rajya Sabha on 08 August, 2022

LOK SABHA SECRETARIAT

NEW DELHI

August, 2022/ Sravana, 1944 (Saka)

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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 Anthiyur P. Selvarasu
26. Shri Arun Singh
27. Shri Vijay Pal Singh Tomar
28. Shri K. Vanlalvena
29. Vacant*
30. Vacant*
31. Vacant

SECRETARIAT

1.	Shri Vinay Kumar Mohan	:	Joint Secretary
2.	Shri Nabin Kumar Jha	:	Director
3.	Shri Kulvinder Singh	:	Deputy Secretary
4.	Ms Sonia Sankhla	:	Executive Officer

* Vacant *vice* Shri M.V. Shreyams Kumar (LJD), MP (RS) retired on 02.04.2022 from the Membership of Rajya Sabha. (RSS I.D. No. 1(2)/2019- Coord dated 18.01.2022).

* Vacant *vice* Shri Jaiprakash Nishad (BJP), MP (RS) retired on 04.07.2022 from the Membership of Rajya Sabha. (RSS I.D. No. 1(2)/2019- Coord dated 18.01.2022).

INTRODUCTION

I, the Chairperson, Standing Committee on Chemicals and Fertilizers (2021-2022) having been authorized by the Committee, do present on their behalf this Thirty-Fifth Report on Action taken by the Government on the Observations/Recommendations of the Committee contained in their Thirty-First Report (Seventeenth Lok Sabha) on 'Availability of Medicines & Medical devices for COVID Management' pertaining to the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

2. The Thirty-First Report was presented to Lok Sabha and laid in Rajya Sabha on 21st March, 2022. The Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) furnished their replies on 29th June, 2022 indicating Action Taken on the Observations/Recommendations contained in the Thirty-First Report. The Committee considered and adopted the Draft Report at their sitting held on 4th August, 2022.

3. An analysis of the Action Taken by the Government on the Observations/Recommendations contained in the Thirty-First Report (Seventeenth Lok Sabha) of the Committee is given in **Appendix-II.**

4. For ease of reference, Observations/Recommendations of the Committee have been printed in bold letters in the Report**.**

New Delhi;
08 August, 2022
13 Sravana, 1944 (Saka)

KANIMOZHI KARUNANIDHI
CHAIRPERSON,
STANDING COMMITTEE ON
CHEMICALS & FERTILIZERS.

REPORT

CHAPTER – I

This Report deals with the action taken by the Government on the Observations/ Recommendations of the Committee contains in their Thirty-First Report (17th Lok Sabha) on 'Availability of Medicines & Medical devices for COVID Management' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).

1.2 The Thirty-First Report was presented to Lok Sabha and laid in Rajya Sabha on 21 March 2022. It contained 19 Observations/Recommendations. Replies of Government in respect of all the Recommendations have been received and are categorized as follows:-

(i) Observations / Recommendations that have been accepted by the Government:-

Sl.Nos.1,2,3,4,5,7,11,12,13,14,15,16,17,18 (Total=14)

These are included in Chapter II of the Report.

(ii) Observations / Recommendations which the Committee do not desire to pursue in view of the Government's reply:-

Sl.No. 6 (Total = 1)

These are included in Chapter III of the Report.

(iii) Observations / Recommendations in respect of which replies of the Government have not been accepted by the Committee and require reiteration:-

Sl.Nos. 8,9,10,19 (Total = 4)

These are included in Chapter IV of the Report.

(iv) Observations / Recommendations in respect of which final replies of the Government are still awaited:-

Sl.No. NIL (Total=0)

These are included in Chapter V of the Report.

1.3 The Committee desire that the Action Taken Notes on the observations/recommendations contained in Chapter-I of this Report may be furnished expeditiously and not later than three months from the date of presentation of this Report.

1.4 The Committee will now deal with action taken by the Government on the Recommendations/Observations which still require reiteration or merit further comments.

RECOMMENDATION No. 8

Nationwide Training Programme for Rational Use of COVID treating medicines

1.5 While stressing on the need for nationwide training programme for rational use of COVID treating medicines, the Committee had recommended as under:-

> "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 subgroup 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."

REPLY OF THE GOVERNMENT

1.6 In reply to the above recommendation of the Committee, the Department of Pharmaceuticals has stated as under:-

> "MoH&FW had issued a separate 'Advisory on rational use of Remdesivir for COVID-19 treatment' on 7th June 2021, which was hosted on its website for wider dissemination. Further noting 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 (DGHS). Standard treatment guidelines were also disseminated through MoHFW's Center 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."

FURTHER COMMENTS OF THE COMMITTEE

1.7 The Committee note that the MoH&FW has only issued advisories on rational use of Remdesivir, steroids and other immunosuppressive drugs to promote rational use of COVID related drugs among State level/Regional centres of excellence as well as private doctors. However, the reply furnished by the Department is silent on the recommendation of the Committee 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. In this regard, the Committee hope that the Union Government in coordination with State Government will explore the possibility of conducting such training programme so that the guidelines on rational use of drugs can be complimented with practical knowhow among the doctors and best practices can be shared among public and private hospitals through such training programme. The Committee would like to be informed about the action taken on this recommendation in the Final Action Taken Reply.

RECOMMENDATION No. 9

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

1.8 With regard to Prompt Action Against Hoarding/Black Marketing/Over Pricing of Medicines and Medical Devices, the Committee had recommended as under:-

"(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."

REPLY OF THE GOVERNMENT

1.9 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:-

"(a) and (b): Action is initiated by NPPA, under aegis of DoP, on any case that is reported of overpricing in the case of medicines and medical devices as per the provisions of DPCO, 2013. So far as cases of hoarding and black-marketing are concerned, the then Chairman, NPPA vide her D.O. letter dated 23rd April 2021 had requested DCGI to take strict measures for prevention of black-marketing and hoarding of essential drugs. State level team formation has also been urged for field level action monitoring. NPPA has also written a DO letter on 8th April, 2021 to all the State Drug Controllers to closely monitor

the production and availability of COVID 19 drugs, prevent black-marketing and hoarding, and ensure availability of life saving essential drugs.

In addition, various regulatory actions were taken by CDSCO against hoarding/black marketing/over pricing of medicines and medical devices related to COVID-19, which are detailed as under:

i. To ensure availability of Covid drugs in the country, CDSCO has requested all State/UT Drugs Controllers to take all proactive steps, i.e., monitoring stockpiling, maintaining checks on availability of drugs, random market survey of critical drugs for used in COVID- 19.

ii. All the States/UTs Drugs Controllers were requested to take necessary steps to expedite issuance of permissions/approvals for manufacturing and issuance of other approvals so that supply chain is not affected.

iii. Based on the complaint received from MoH&FW, regarding shortage of Remdesivir injection in certain areas in Madhya Pradesh (Bhopal, Indore, Gwalior), Gujarat (Ahmedabad, Surat, Rajkot) and Maharashtra (Mumbai, Thane, Ambernath). CDSCO wrote to all State / UT Drugs Controllers requesting to initiate immediate remedial action to ensure supply of Remdesivir injection to public and private hospitals and also to instruct their enforcement officials to keep continuous monitoring on the situation and keep strict vigil on the matter.

iv. CDSCO has requested to all State / UT Drugs Controllers to instruct their enforcement staff immediately to keep strict vigil especially at sensitive places and to take stringent action against hoarding/black marketing/overcharging for Remdesivir by conducting special drive of monitoring and investigation, so that such incidence could be prevented.

v. CDSCO also requested all State / UT Drugs Controllers to forward information in the given format on a daily basis with regard to enforcement activities to prevent hoarding/black marketing /overcharging / overpricing in respect of Remdesivir, Tocilizumab, Favipiravir and Oxygen Cylinder.

vi. With reports on black marketing/hoarding of COVID related drugs, CDSCO has requested all State/UT Drugs Controllers to instruct their enforcement staff to keep strict vigil on the matter especially at sensitive places and to take stringent action against hoarding/black marketing/overcharging of drugs by conducting special drive of monitoring and investigation, so that any such incident of drugs is prevented. It was also stated that there shall be zero tolerance for any kind of hoarding/black-marketing/overcharging of drugs. It was requested to establish a special task force for the purpose and also nominate a nodal officer in their respective States and UTs to attend to all complainants and intelligence inputs. CDSCO carried out a weekly availability survey of 17 drugs/ devices/ items near Covid designated hospitals and general chemist shops. Its frequency was increased to twice a week when required."

1.10 The Committee note that the Ministry has informed about a number of measures initiated by National Pharmaceuticals Pricing Authority (NPPA) on

cases of overpricing of medicines and medical devices as per the provision of Drugs (Price Control) Order (DPCO), 2013. NPPA has also requested Drug Controller General of India (DCGI) to take strict measures for prevention of black-marketing and hoarding of essential drugs. Further all the State Drug Controllers have also been requested to closely monitor the production and availability of (i) COVID-19 drugs (ii) to prevent black-marketing & hoarding and (iii) ensure availability of life saving essential durgs. However the Committee are surprised to note that the number of cases of overpricing of medicines/medical devices, black-marketing/hoarding of essential drugs has not been furnished. In view of the Committee after an analysis of figures of cases of overpricing of medicines/medical devices, black/marketing etc. reported during the last two to three years the efficacy of these measures can be judged. Apart from this the details of not even a single complaint of Remdesivir injection has been furnished to the committee, although according to the Department the Ministry of Health and Family Welfare had lodged a complaint to Department of Pharmaceuticals regarding shortage of Remdesivir injection in certain areas of Madhya Pradesh, Maharashtra and Gujarat. The Committee recommend that a detailed report about such complaints and their disposal be immediately furnished for their consideration. The Committee also note with concern that the reply of the Ministry is silent on the steps taken to increase awareness among the people about the complaint/grievance redressal mechanism available to them so that they can report matters related to overpricing/hoarding/black marketing as recommended by the Committee. The Committee strongly reiterates its recommendation and recommend that NPPA and CDSCO should take urgent steps in this regard.

RECOMMENDATION No. 10

<u>Effective price control of Non-schedule COVID-19 related Medicines and Medical Devices</u>

1.11 With regard to effective price control of Non-schedule COVID-19 related Medicines and Medical Devices, the Committee had recommended as under:

> "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 ofthe 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."

REPLY OF THE GOVERNMENT

1.12 In reply to the above recommendation of the Committee, the Department of Pharmaceuticals has stated as under:-

"Based on the principles laid down in the National Pharmaceuticals Pricing Policy, 2012 (NPPP, 2012), the government has issued the Drugs Prices Control Order, 2013 (DPCO, 2013). The medicines included in the National list of Essential Medicines (NLEM) issued by the MoH&FW are included in the Schedule-I of DPCO, 2013. While the ceiling prices of Scheduled formulations are fixed by NPPA under DoP, in respect of other medicines (non-scheduled), NPPA ensures that their MRP is not increased by more than ten percent of what was prevalent during the preceding twelve months. Price control of non-scheduled medicines will entail revision of NPPP, 2012 and DPCO, 2013."

FURTHER COMMENTS OF THE COMMITTEE

1.13 The Committee is disheartened to note that the Department has failed to convert this pandemic situation into an opportunity to make the current Drugs Price Control Regime flexible and insert clauses that address price control of non-schedule COVID-19 related medicines and medical devices. The Department has stated that price control of non-scheduled medicines will entail revision of National Pharmaceutical Pricing Policy (NPPP), 2012 and Drug (prices control) Order (DPCO), 2013. The Committee believes that the Department of Pharmaceuticals has full authority as well as responsibility to make changes in these policies/orders and some concrete action has to be taken in this respect to provide affordable medicines and medical devices in the country during pandemic like health crisis. The Committee therefore, reiterates its recommendation with respect to formulation of new price control regime or amend the current price control order, specific for COVID/future pandemic related medicines and medical devices.

RECOMMENDATION No. 19

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

1.14 The Committee had given following recommendation with respect to 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."

REPLY OF THE GOVERNMENT

1.15 In reply to the above recommendation of the Committee, the Department of Pharmaceuticals has stated as under:-

"Department of Revenue, Ministry of Finance has provided inputs regarding exemption of Basic Customs Duty and GST on medicines and medical devices for fighting COVID 19, as below. While **Table A** shows the list of items that were provided exemption from Basic Customs Duty, the notifications under which the exemptions were provided and the validity of the notifications, the **Table B** shows the exemption from GST and reduction in GST rates provided for COVID-19 related relief goods, the notifications under which the exemptions were provided and the validity of the notifications.

TABLE A Full Exemption from Basic Customs Duty on import of COVID 19 relief goods

S.No.	Description of goods	Valid till	Reference
1.	Face Mask and Surgical Mask	30th September, 2020	Notification No. 20/2020-Customs dated 9th April, 2020
2.	Personal protective Equipment (PPE)		
3.	Covid-19 Testing Kits		
4.	Remdesivir Active Pharmaceutical Ingredients (API)	31.10.2021	Notification No. 27/2021-Customs dated 20.04.21, as amended *vide* notification No. 29/2021-Customs dated 30.04.21
5.	Beta Cyclodextrin (SBEBCD) used in manufacture of Remdesivir, subject to the condition that the importer follows the procedure set out in the Customs (Import of Goods at Concessional Rate of Duty) Rules, 2017.	31.10.2021	
6.	Injection Remdesivir.	31.10.2021	
7.	Inflammatory Diagnostic (marker) kits, namely- IL6, D-Dimer, CRP(C-Reactive Protein), LDH (Lactate De-Hydrogenase), Ferritin, Pro Calcitonin (PCT) and blood gas reagents	31.10.2021	

8.	Medical Oxygen	31.08.2021	
9.	Oxygen concentrator including flow meter, regulator, connectors and tubings.	31.08.2021	
10.	Vacuum Pressure Swing Absorption (VPSA) and Pressure Swing Absorption (PSA) oxygen plants, Cryogenic oxygen Air Separation Units (ASUs) producing liquid/gaseous oxygen.	31.08.2021	
11.	Oxygen canister.	31.08.2021	
12.	Oxygen filling systems.	31.08.2021	
13.	Oxygen storage tanks	31.08.2021	
14.	Oxygen generator	31.08.2021	
15.	ISO containers for Shipping Oxygen	31.08.2021	
16.	Cryogenic road transport tanks for Oxygen	31.08.2021	
17.	Oxygen cylinders including cryogenic cylinders and tanks	31.08.2021	Notification No. 28/2021-Customs dated 24.04.21, as amended *vide* notification No. 31/2021-Customs dated 31.05.21[#]
18.	Parts of goods at S.No.6 to 14 above, used in the manufacture of equipment related to the production, transportation, distribution or storage of Oxygen, subject to the condition that the importer follows the procedure set out in the Customs (Import of Goods at Concessional Rate of Duty) Rules, 2017.	31.08.2021	
19.	Any other device from which oxygen can be generated	31.08.2021	
20.	Ventilators, including ventilator with compressors; all accessories and tubings; humidifiers; viral filters (should be able to function as high flow device and come with nasal canula).	31.08.2021	
21.	High flow nasal canula device with all attachments; nasal canula for use with the device.	31.08.2021	
22.	Helmets for use with non-invasive ventilation.	31.08.2021	

23.	Non-invasive ventilation oronasal masks for ICU ventilators.	31.08.2021	
24.	Non-invasive ventilation nasal masks for ICU ventilators.	31.08.2021	
25.	COVID-19 vaccine.	31.08.2021	
26.	Amphotericin B	31.08.2021	
27.	Full exemption from Basic Customs Duty on 6 specified API/ excipients for manufacturing Amphotericin B	31.08.2021	Notification No. 35/2021-Customs dated 12th July, 2021
28.	Full exemption from Basic Customs Duty on Raw materials for manufacturing COVID test kits	30.09.2021	

TABLE B Exemption/ Reduction in GST/ IGST on import of COVID-19 relief goods

S.No.	Description of goods	Reduced GST rate	Valid till	Reference
1.	All goods covered under Customs notification 27/2201 and 28/2021 (listed in Table 1 above), imported by State Government or agency authorised by it, free of cost for free distribution.	Nil	31.08.2021	Ad hoc exemption Order (AEO) No. 4/2021-Customs dated 03.05.2021, as amended by AEO No. 5/2021-Customs dated 31.05.2021
2.	All goods covered under Customs notifications 27/2201 and 28/2021 (listed in Table 1 above), imported and donated to Central/ State Government or relief agency recommended by State Government, for free distribution.	Nil	31.08.2021	Notification No. 32/2021-Customs dated 31.05.2021
3.	Medical Grade Oxygen	5%	30.09.2021	Notification No. 05/2021-Central Tax (Rate) dated 14.06.2021
4.	Tocilizumab	Nil	30.09.2021	
5.	Amphotericin B	Nil	30.09.2021	
6.	Remdesivir	5%	30.09.2021	
7.	Heparin (anti-coagulant)	5%	30.09.2021	
8.	Covid-19 testing kits	5%	30.09.2021	
9.	Inflammatory Diagnostic (marker) kits, namely- IL6, D-Dimer, CRP (C-Reactive Protein), LDH (Lactate De-Hydrogenase), Ferritin, Pro Calcitonin (PCT) and blood gas reagents.	5%	30.09.2021	
10.	Hand Sanitizer	5%	30.09.2021	

S.No.	Description of goods	Reduced GST rate	Valid till	Reference
11.	Helmets for use with non-invasive ventilation	5%	30.09.2021	
12.	Gas/Electric/other furnaces for crematorium	5%	30.09.2021	
13.	Pulse Oximeter	5%	30.09.2021	
14.	High flow nasal canula device	5%	30.09.2021	
15.	Oxygen Concentrator/ generator	5%	30.09.2021	
16.	Ventilators	5%	30.09.2021	
17.	BiPAP Machine	5%	30.09.2021	
18.	Non-invasive ventilation nasal or oronasal masks for ICU ventilators Canula for use with ventilators	5%	30.09.2021	
19.	Temperature check equipment	5%	30.09.2021	
20.	Ambulance	12%	30.09.2021	

FURTHER COMMENTS OF THE COMMITTEE

1.16 The Committee note that all the items listed in Table A like face mask and surgical mask, PPE, Covid-19 testing kit etc. mentioning full exemption from Basic Customs Duty and Table B showing exemption/ reduction in GST/ IGST on import of COVID-19 relief goods have surpassed their validity in 2021 itself. However the Committee had recommended the Department to explore the possibility of providing these exemptions till the pandemic is over. The Committee feel that these exemptions should have continued till the pandemic is over. The Committee, therefore strongly reiterates its recommendation on exemption of Basic Customs Duty and GST on medicines and medical devices for fighting COVID 19 till the pandemic is over.

CHAPTER II

OBSERVATIONS / RECOMMENDATIONS WHICH HAVE BEEN ACCEPTED BY THE GOVERNMENT

RECOMMENDATION No. 1

Availability of required quantum of medicines

2.1 With regard to the Availability of required quantum of medicines, the Committee had recommended as follows:-

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 inactive 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 inimports 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.

REPLY OF THE GOVERNMENT

2.2 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:-

1(a) Ministry of Health & Family Welfare has informed that the National Drug Buffer Management Guidelines/Strategy for all the essential drugs used in the COVID treatment were prepared from time to time to ensure availability of Covid-19 related drugs in emergency situation. The guidelines were formulated and communicated to States/ UTs vide MoHFW's DO Letter No X.11035/178/2021-DRS dated 13th July, 2021. Further, an online monitoring portal www.dvdms.in was developed to capture information with respect to Stocks, Purchase Orders and Closing stock of 8 critical drugs with states including, Enoxaparin 40mg, Methyl Prednisolone Injection 40mg/ml, Dexamethasone Injection 4mg/ml, Remdesivir Injection 100mg/vial, Tocilizumab Injection 400mg, Amphotericine B Deoxycholate Injection 50mg/Vial Posaconazole Injection 300mg, IVIG Injection 10.

Daily training sessions were conducted for uploading information on portal. A WhatsApp group of all nodal officers of states has been created for immediate response. Further, training Program on MIS System started on 9th Sep 2021 and is being held every day at 3 PM (Monday to Friday) till date. Moreover, daily track is kept regarding the availability of buffer Stock of 8 essential medicine used in management of Covid-19.

In pursuance of the M/o H&FW's guidelines dated 13th July 2021 emphasizing the States to build up the buffer stocks of prescribed drugs to strengthen the preparedness to meet any future surge of Covid cases, the Department of Pharmaceuticals (DoP) assigned the National Pharmaceutical Pricing Authority (NPPA) to coordinate with States/ UTs and the manufacturers to monitor the supplies once the purchase orders were placed by the State/UT governments. Accordingly, NPPA has actively coordinated with manufacturers and States/UTs to ensure availability of adequate stock of Covid drugs, including IVIG.

1(b) Ministry of External Affairs (MEA) has informed that the Indian manufacturers of COVID-19 medicines have been provided all necessary support in terms of logistics and import of raw materials by MEA and its Missions abroad to enable them to manufacture the required quantum of medicines.

Pursuant to Government's call to ramp up domestic production of Remdesivir to 1 crore doses a month, the Indian manufacturers had sought Ministry's help in sourcing critical raw materials from countries abroad, mainly from China, United States and Europe. Missions and Posts reached out to the suppliers and also sought support from foreign governments. A sustained effort was made to speed up delivery schedules. Specifically, the Indian missions in US, France, Germany, Italy, Hungary, Portugal and China successfully took up the suppliers in these countries to expedite supply of raw material, expand their production capacity, etc. so as to expedite delivery.

MoH&FW has informed that the Central Drugs Standard Control Organisation (CDSCO) streamlined the various regulatory procedures to ensure patient safety, early access to medicine as well as ease of doing business through issuance of various circulars, notices, orders etc. The details of measures taken to streamline regulatory procedures are as under: -

(i) On 30.01.2020, the World Health Organization (WHO) had declared the outbreak of coronavirus as a "Public Health Emergency and subsequently, on 11.03.2020 declared it as a pandemic, and reiterating the call for countries to take immediate actions and scale up response to treat, detect and reduce the transmission.

(ii) To ensure adequate supply of the essential medicines, the issue was taken up with the State Governments as well as various drug manufacturing associations also, to ensure that they were having enough stock of APIs and formulations and there were no shortages of essential medicines.

(iii) Government has also issued advisory to all the State/UT Governments to ensure that merchant importers/ stockists as well as indigenous manufacturers of APIs do not hoard and create artificial scarcity of APIs / KSMs in the country.

(iv) CDSCO has so far, approved total 515 diagnostic kits for COVID -19 on fast track basis which includes 262 RT PCR kits, 155 Rapid antibody kits, 85 Antigen test kit and 13 Antigen home test kit.

(v) Govt. has issued notification on 18th May, 2020 so that manufacturers 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 approval by CDSCO for manufacturing.

(vi) Considering the emergency and unmet medical need, CDSCO approved the following five drugs for Restricted Emergency Use in the country for treatment of COVID-19 infection:

a. Remdesivir Injectable formulations for treatment of patients with severe COVID-19 infection, initially on 01.06.20 for import and marketing and subsequently, for manufacture and marketing the same drug to three indigenous manufacturers.

b. Manufacturing and marketing permission on 19.06.2020 for Favipiravir tablets for mild to moderate COVID-19 infection.

c. Marketing permission 10.07.20 for Itolizumab injection for the treatment of CRS in moderate to severe ARDS patients due to COVID-19.

d. Manufacturing and marketing permission on 28.12.2021 for Molnupiravir capsules for treatment of adult patients with COVID-19, with SpO2 >93% and who have high risk of progression of the disease including hospitalization or death.

e. Manufacturing and marketing permission on 21.04.2022 for Nirmatrelvir tablets and Ritonavir tablets for treatment of adult patients with COVID19, with SpO2 >93% and who have high risk of progression of the disease including hospitalization or death.

(vii) The Government has assessed and ensured the availability of the essential medicines, hand sanitizers as well as protective equipment including masks, PPE Kits as well as fast track processing of applications for clinical trials and new drug including vaccines for COVID and taken all possible measures to meet the public health emergency for COVID.

(viii) CDSCO has granted approval to ten vaccines for manufacture for sale or distribution in the country with certain regulatory conditions.

(ix) Provisions regarding the doorstep delivery of drugs to consumers under Section 26B of the Drugs and Cosmetics Act, 1940, published vide G.S.R. 220(E) dated 26.03.2020 are applicable only for retail chemists having retail sale license in Form-20 or Form-21 under the Drugs and Cosmetics Rules, 1945. It is not applicable for any digital health platforms/e-pharmacy/online pharmacy platforms.

In order to handle the unexpected pandemic of Covid-19 in Jan 2020 onward and to ensure the continuous production and availability of the Covid drugs in the country, DoP in co-ordination with the NPPA & CDSCO have taken up various issues with the State/UT Governments, Drugs Controllers, industry associations including Chemist and Druggist Associations to take necessary measures to facilitate the drugs and pharmaceutical manufacturing companies for smooth movement of raw materials, packaging materials etc. as well as movement of the required personnel to maintain smooth supply chain of drugs in the country.

DoP in collaboration with NIC and CDSCO has developed a CDMS (COVID Drugs Monitoring System) Portal to monitor the availability of indigenously manufactured and imported APIs and formulations used in COVID management. Stocks of API along with stocks of KSM/Intermediates are captured in the portal on weekly and monthly basis.

1(c) Ministry of Health & Family Welfare has informed that currently the JWG is responsible for creation/ updation of National Treatment Protocol for Covid-19 Management. If required, representative from DoP will be invited as special representative. ICMR has also informed about nomination of an officer from DoP.

RECOMMENDATION No. 2

Major constraints in ensuring availability of medicines

2.3 With regard to the Major constraints in ensuring availability of medicines, the Committee had recommended as follows:-

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 takestwo 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 allthe 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, Indianmissions 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.

REPLY OF THE GOVERNMENT

2.4 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:-

(a) National Drug Buffer Management Guidelines/Strategy for all the essential drugs used in the COVID treatment were prepared from time to time to ensure the availability of Covid-19 related drugs in emergency situation. Further, an online monitoring portal www.dvdms.in was developed to capture information with respect to Stocks, Purchase Orders and Closing stock of 8 critical drugs with States including, Enoxaparin 40mg, Methyl Prednisolone Injection 40mg/ml, Dexamethasone Injection 4mg/ml, Remdesivir Injection 100mg/vial, Tocilizumab

Injection 400mg, Amphotericine B Deoxycholate Injection 50mg/Vial Posaconazole Injection 300mg, IVIG Injection 10. Daily training sessions were conducted for uploading information on portal. Further, daily track was kept regarding the availability of buffer Stock of 8 essential medicine used in management of Covid-19.

(b) CDSCO and MoH&FW took the following regulatory measures to curb the Import dependence:

(i) CDSCO has issued the advisory to State Licensing Authorities to facilitate increasing the production of COVID drugs and other essential drugs including API from time to time.

(ii) MoH&FW amended the Drugs and Cosmetics Rules, 1945 vide Notification No. G.S.R. 1193 (E) dated 12/12/2018, wherein the application fees have been increased for grant of various Import Registration certificates/Licences/Permission drugs/New drugs as well as Overseas Inspection. This encourages domestic production.

(iii) There is a provision under Rule 24(A)(5) of the Drugs and Cosmetics Rules, 1945, for inspection or visit of the manufacturing premises or drugs, by the licensing authority or by any persons to whom power has been delegated in this behalf by the licensing authority under Rule 22 of said rules.

Department of Pharmaceuticals (DoP) has framed a Scheme “Production Linked Incentive (PLI) Scheme for Promotion of domestic Manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates and Active Pharmaceutical Ingredients (APIs) in the Country” with objective to attain self-reliance and reduce import dependence in critical KSMs/DIs/APIs. Under the Scheme, financial incentives are given based on committed investment and sales made by selected applicant for the eligible products. The 41 eligible products under the Scheme covers the 53 APIs approved by the Government. Out of 239 applications received under the scheme, 49 applications have been approved for 33 products. Further, the DoP has also launched a Scheme for “Promotion of Bulk Drug Parks” with objective to promote setting up of Bulk Drugs parks in the country for providing easy access to world class Common Infrastructure Facilities (CIF) to bulk drug units located in the park in order to significantly bring down the manufacturing cost of bulk drugs and thereby make India self-reliant in bulk drugs by increasing the competitiveness of the domestic bulk drug industry. Thirteen applications received under the Scheme are under examination.

(c) MEA has informed that the Indian Missions abroad have been extending all necessary assistance to the Indian manufacturers in getting the raw materials, including excipients from the overseas suppliers for manufacturing COVID-19 drugs.

The Indian Missions were able to get immediate positive response from as many as 23 suppliers in 13 countries for supply of Remdesivir, either as donation or for

commercial purchase. It also helped in sourcing critical raw materials from countries abroad, mainly from China, United States and Europe, which helped in ramping up production in India. With MEA's intervention, the Allocation of Tocilizumab was significantly expanded by M/s Roche, which immediately supplied 50,000 vials to India, promised to ship another 50,000 vials in subsequent weeks, expanded production and doubled delivery. MEA also worked with external manufacturers on transferring technologies to further increase global Actemra (Tocilizumab) supply as quickly as possible. MEA also helped in identifying suppliers for Molnupirapir within a very short span of time.

RECOMMENDATION No. 3

Covid Drugs Management Cell (CDMC)

2.5 With regard to the Covid Drugs Management Cell (CDMC), the Committee had recommended as follows:-

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.

REPLY OF THE GOVERNMENT

2.6 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:-

(a) to (f) DoP, along with NPPA and CDSCO has set up CDMC. As recommended by the Committee, CDMC is still functioning and its meetings are being conducted at periodic intervals. While, during the peak of the pandemic situation, six officers including an Additional Secretary level officer were attached with the department, but with reduction in number of active cases, DoP is able to manage things with the human resources available at its disposal. However, if required, it will again request DoP&T for posting officers, as needed. CDMC with its continuous watch on monitoring activities by the government agencies like NPPA and CDSCO has ensured the sufficient availability of medicines and medical devices to all States/ UTs as per their requirements. During the peak pandemic period, CDMC undertook the exercises of allocation of Remdesivir, Tocilizumab and Amphotericin to different States / UTs / Central Agencies and PSEs. This facilitated equitable distribution of these medicines to different parts of the country. Moreover, continuous monitoring of 8 buffer drugs identified by MoH&FW plus other drugs totalling to more than 30 in number along with the crucial medical devices are being done to keep close watch on their availability in hospitals and general chemist shops. The suggestion of opening similar cell as CDMC at state level has been noted and the same will be undertaken, if such need arises.

RECOMMENDATION No. 4

Drugs Coordination Committee (DCC)

2.7 With regard to the Drugs Coordination Committee (DCC), the Committee had recommended as follows:-

(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.

REPLY OF THE GOVERNMENT

2.8 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:-

(a) and (b): DoP had set up DCC with representatives taken from MoHFW, DGHS, ICMR, DGFT, MEA, CDSCO and NPPA for efficient decision making on all the issues with respect to COVID-19 related drugs. Till date, eleven meetings of DCC have been held. Presently, no surge in active cases has been noted. In case of any surge in active cases, the DCC will meet, as and when required, to make available the medicines and medical devices required for COVID-19.

RECOMMENDATION No. 5

Empowered Group-2 (EG-2)

2.9 With regard to the Empowered Group-2 (EG-2), the Committee had recommended as follows:-

(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.

REPLY OF THE GOVERNMENT

2.10 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:-

(a) and (b): DoP had assigned NPPA to coordinate with States/ UTs and the manufacturers to monitor the supplies once the purchase orders were placed by the State/UT governments. NPPA has actively coordinated with manufacturers and States/UTs to ensure availability of adequate stock of Covid drugs, including IVIG. In order to ensure domestic availability, on 8.2.2020, all personal protective equipment (PPE) including clothing, masks, coveralls, N95 Mask were prohibited for export. Export of Ventilators/surgical Mask, Disposable banned on 19.3.2020 while Hydroxychloroquine (HCQ) and formation export were banned on 25.3.2020. Subsequently, in view of improvement in Covid 19 situation and adequate availability of domestically produced essential medical equipment ban on export of Ventilators was removed on 4.8.2020; of PPE on 25.8.2020; of N95 Masks on 6.10.2020; of Sanitizers on 15.10.2020 and that of Goggles/Nitrile Gloves on 22.12.20.

MoHFW along with DoP took various initiatives to ensure the availability of medicines in the country. EG-2 took various actions to ramp up its efforts to import the medicines like Tocilizumab, Liposomal Amphotericin B etc. which are mostly imported.

In order to maintain the availability of stock for domestic use during the COVID-19 pandemic, the export of Injection Remdesivir and Remdesivir Active Pharmaceutical Ingredients (API), Amphotericin-B injections, Enoxaparin (Formulation and API) and Intra-Venous Immunoglobulin (IVIG) (Formulation and API) was restricted vide DGFT's Notifications No. 08/2015-2020 dated 14.06.2021, 07/2015-2020 dated 01.06.2021 and 15/2015-2020 dated 10.01.2022 respectively. Further, looking at the declining trend of new COVID cases as well as cumulative active cases, the restrictions on above four drugs were lifted. If there is any surge in active cases, appropriate decision will be taken up by the Empowered Group-2.

RECOMMENDATION No. 7

Shortage of Remdesivir during the second wave of pandemic

2.11 With regard to the Shortage of Remdesivir during the second wave of pandemic, the Committee had recommended as follows:-

(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 2021to 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 toensure fair and equitable distribution across the country. MoHFW has also suppliedaround 30,10,798 Remdesivir vials, free of cost, to the States/UTs to address COVIDpandemic.In the aftermath of the second wave, the demand for Remdesivir has come down considerably and the demand supply gap has reversed whereby supplyis much more than the demand. Accordingly, Remdesivir was moved fromProhibited to Restricted Category of Exports on 14th June, 2021. The states and UTshave been issued "Guidelines for Buffer Stock Management of Covid-19 Drugs"and advised to procure and maintain buffer stocks of Remdesivir and other

Drugsfor preparedness to deal with any future requirements. Since Remdesivir has beenincluded in the National Treatment Protocol as only an optional drug, theCommittee 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. Basedon the studies, steps should be taken by MoHFW to remove those drugs which arenot 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 thestreet is suffering either due to non availability of Remdesivir or if available, anexorbitant price is charged making it difficult for the poor people to afford the medical treatment. However, the Committee fail to understand that none of thePharma Public Sector Undertakings under the Department of Pharmaceuticals havebeen granted voluntary license to manufacture Remdesivir and other COVIDessential drugs for public health supply. In this regard, the Committee feel thatequal opportunity should also be extended to these Pharma PSUs who havedeveloped trust, quality and cost effectiveness in their pharma products over a longperiod of time. The Committee, therefore, recommend that the Department ofPharmaceutical initiate steps to explore the possibilities of manufacturing of COVID essential drugs by PSUs under it.

REPLY OF THE GOVERNMENT

2.12 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:-

(a) and (b) National Treatment Protocol is decided by DGHS, which updates the same from time to time. All the five pharma PSUs under the aegis of the Department of Pharmaceuticals are under closure or strategic sale. However, private manufacturers have come forward and seven of them, viz., Mylan Pharmaceuticals Pvt. Ltd., Jubilant Generics Ltd., Hetero Healthcare Ltd., Cadilla Health Care Ltd., Syngene International Ltd. (Biocon Biologics India), Dr. Reddy's Laboratories Ltd. and Cipla Limited got licences from M/s Gilead Life Sciences (USA), the patent holder of the Remdesivir injections to manufacture and market these medicines in India.

RECOMMENDATION No. 11

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

2.13 With regard to India Covid-19 Emergency Response and Health Systems Preparedness Package -Phase-II, the Committee had recommended as follows:-

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.

REPLY OF THE GOVERNMENT

2.14 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:-

MoH&FW has informed that the 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 08.07.2021 for an amount of Rs. 23,123 crores, 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 component of Central Procurement of essential medicines (including the emerging drugs, based on the needs) for effective management of COVID19. An amount of Rs. 680 crore was provided under centrally sponsored portion of ECRP-II to all districts of States to ensure availability of essential drugs including a buffer stock of drugs for Covid-19 management.

RECOMMENDATION No. 12

Risk to children from COVID 19

2.15 With regard to the Risk to children from COVID 19, the Committee had recommended as follows:-

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.

REPLY OF THE GOVERNMENT

2.16 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:-

MoH&FW developed an online monitoring portal, viz., www.dvdms.in to capture information with respect to stocks, purchase orders and closing stock of 8 critical drugs with States/UTs. As explained in reply to Recommendation No. 11 above, funds for the same have also been provided to the states. Further, to strengthen the preparedness to meet any future surge, guidelines for Buffer Stock Management of drugs used for COVID- 19 were shared with the States/UTs, emphasizing the States to initiate procurement on priority for building up buffer

stocks. NPPA was assigned to actively coordinate with States/ UTs and the manufacturers, if any, facilitation is required to monitor supplies, once the purchase orders are placed. NPPA actively coordinated with manufacturers and States/UTs to ensure availability of adequate stock of IVIG.

RECOMMENDATION No. 13

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

2.17 With regard to the Effective Research for better understanding of causes of Mucormycosis/ Black Fungus disease, the Committee had recommended as follows:-

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-19patients. 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.

REPLY OF THE GOVERNMENT

2.18 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:-

ICMR, in 2019, initiated a National Task Force (NTF) for capacity building and institutional strengthening for advanced and standardized fungal diagnostic facilities across the country. Six Advanced Mycology Diagnostic and Research Centres (AMDRCs) have been established through this NTF to improve patient care &

management and fungal research in the centre in their geographical area. NTF was initiated in 12 centres across the country in July 2021 to identify the factors responsible for the development of Mucormycosis. Analysis of the data generated is currently under process in ICMR. Department of Biotechnology (DBT) initiated the efforts at National Centre for Cell Science (NCCS), Pune, to understand the fungal organisms involved in disease incidences of Mucormycosis in the city of Pune. The morphological and sequencing analyses of the collected samples revealed the prevalence of Rhizopusarrizus and R. oryzae among the diagnosed patients. However, few isolates were identified as Aspergillus hortai, A. persii, Peniophora sp., Parathyridariasp., which were rarely reported in case of Mucormycosis. Further studies are proposed to be undertaken by DBT to gain insights into the pathogenesis.

RECOMMENDATION No. 14

Treatment for Mucormycosis/Black Fungus disease

2.19 With regard to the Treatment for Mucormycosis/Black Fungus disease, the Committee had recommended as follows:-

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'ssupply 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, fool proof 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.

REPLY OF THE GOVERNMENT

2.20 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:-

A sudden increase in demand was observed in mid-2021 in some states for Amphotericin-B, which was being actively prescribed by the physicians to patients suffering from Mucormycosis also known as Black Fungus, a post COVID complication. As the complication which was initially confined to Maharashtra and Gujarat, spread among the other States, the availability of the drug vis-à- vis the supply posed a challenge due to which lot of efforts were undertaken to manage the supply and availability of the drug. The Department of Pharmaceuticals jointly with MoHFW took a decision to allocate Liposomal Amphotericin-B, available in the country through five existing domestic manufacturers and one existing importer, to States/UTs till the supply and demand position stabilizes and also to ensure equitable distribution across the country. For ensuring quick supply, additional 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.

All applications submitted by companies for permission to manufacture Amphotericin -B have been considered expeditiously also keeping in mind the safety and efficacy of the drug to be manufactured. CDSCO has given permission to 11 new manufacturers of Liposomal Amphotericin-B. Names of 11 new manufacturers are M/s Emcure, M/s Gufic, M/s Alembic, M/s Lyka and M/s Natco Ltd, M/s Intas, M/s Aspiro Pharma, M/s Dr. Reddy's Labs, M/s Stelis Biopharma, M/s Jodas Expoim and M/s Samarth Life Sciences.

MEA has informed that missions were mobilized to scout for suppliers of the drug abroad as well as for alternative drugs. Based on MoH&FW's recommendations, MEA asked the concerned Missions and Posts to approach various identified sources and seek firm quotations. MEA presented firm quotations received for the desired drugs to EG-2 for its consideration. MEA reached out to M/s Gilead at an appropriately high level to expedite allocation of Liposomal Amphotericin B. It committed to expediting supply of up to 1 million doses to India through M/s Mylan and withdrew stocks from third countries for supply to India.

MEA also helped several Indian manufacturers of Liposomal Amphotericin-B for expeditious supply of key excipients DSPG and HSPC, required in the production of the drug.

As per monitoring data made available by NPPA till 2nd January 2022, the total number of 16,99,452 vials of L-Amphotericin B injections were supplied to the different States, UTs and Central Agencies, against the total number of 16,08,291 vials allotted to them. As the cases have dropped sharply, this supply shows comfortable position of availability.

RECOMMENDATION No. 15

Provide Quality and Affordable Medical Oxygen in all States/UTs

2.21 With regard to the Provide Quality and Affordable Medical Oxygen in all States/UTs, the Committee had recommended as follows:-

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.

REPLY OF THE GOVERNMENT

2.22 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:-

Department for Promotion of Industry & Internal Tarde (DPIIT), through Petroleum and Explosives Safety Organization (PESO), prepared a national database and portal providing real time availability of liquid oxygen, liquid Oxygen manufactured, supplied to hospital, re-fillers and to industries, which remain functional 24 X 7. All the liquid oxygen manufacturers in the country submitting data on daily basis, were mapped. As on 31.03.2022, the aggregate capacity of cryogenic storage tanks installed in hospitals is 17,085 MT. Similarly, Cryogenic tankers with aggregate carrying capacity of 20,453 MT are available in the country for transportation of liquid oxygen. A daily report on liquid oxygen inventory in the country was submitted for perusal of sub-group of the Empowered Group (EG-4).

MoH&FW monitored and worked in close co-ordination with States and other stakeholders concerned in order to augment the Medical Oxygen infrastructure

across the country in COVID-19 emergency. With regard to Pressure Swing Adsorption (PSA) Oxygen Generation Plants, a total of 1225 plants have been successfully commissioned across 736 districts of 36 States/UTs till date through PMCARES fund. In addition to this, 273 PSA plants out of 283 sanctioned by Central Government PSUs, 49 PSA plants out of 53 sanctioned by Foreign Aid and 2528 PSA plants out of 2583 sanctioned by State /GSR have been commissioned. Thus, a total of 4075 out of 4144 PSA Plants through various sources have been commissioned in the country.

RECOMMENDATION No. 16

Price of Oxygen Concentrators

2.23 With regard to the Price of Oxygen concentrators, the Committee had recommended as follows:-

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 thiscontinuously be an unaffordable medical device for the majority of the people inthe 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.

REPLY OF THE GOVERNMENT

2.24 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:-

With an aim to regulate the prices of medical devices, essential for diagnostic purposes, in general and specifically for COVID-19 management, NPPA, on recommendation of Standing Committee on Affordable Medicines and Health Products (SCAMHP), NITI Aayog, vide Gazette Notification dated 3rd June 2021 capped the trade margin for Oxygen Concentrators at 70% on Price to Distributor (PTD) level. Price reduction in 70/252 products was observed and retail prices reduced up to 54% (up to Rs. 54,337). Similarly, vide notification dated 13th July, 2021, trade margin on Pulse Oximeter, Glucometer, Blood Pressure Monitor, Nebulizer and Digital Thermometer was capped at 70%.

RECOMMENDATION No. 17

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

2.25 With regard to the Covering medical devices for COVID 19 treatment under National List of Essential Medicines, the Committee had recommended as follows:-

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.

REPLY OF THE GOVERNMENT

2.26 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:-

MoH&FW has constituted the Standing National Committee on Medicines (SNCM) for revision of National List of Essential Medicines (NLEM) including medical devices on 3rd July 2018. SNCM is deliberating on the issue and has constituted a sub-committee for Medical Devices. NPPA has capped the trade margin for Ventilators, Oxygen Concentrators, Pulse Oximeter, Glucometer, Blood Pressure Monitor, Nebulizer and Digital Thermometer. As all pharma PSUs are either under closure/ strategic disinvestment, none of them is in manufacture of medical devices for COVID.

RECOMMENDATION No. 18

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

2.27 With regard to the Real time web platform on availability of COVID Medicines and Medical Devices, the Committee had recommended as follows:-

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.

REPLY OF THE GOVERNMENT

2.28 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:-

MoH&FW developed an online monitoring portal, viz., www.dvdms.in to capture information with respect to stocks, purchase orders and closing stock of 8 critical drugs with States/ UTs. Training were provided to state functionaries to upload the data on the portal. NPPA is also working along with CDSCO for getting the up-dated information.

CHAPTER – III

OBSERVATION / RECOMMENDATION WHICH THE COMMITTEE DO NOT DESIRE TO PURSUE IN VIEW OF THE GOVERNMENT'S REPLY

RECOMMENDATION No. 6

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)

3.1 With regard to the 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), the Committee had recommended as follows:-

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 NodalOfficers of States/ UTs and manufacturers to coordinate supplies. CDSCO, throughits Zonal and Sub-zonal offices conducts survey on availability ofHydroxychloroquine, Enoxaparin, Methyl Prednisolone (MP), Paracetamol,Dexamethasone, Budesonide, Ivermectin, Naproxen, Doxyxycline, Azithromycin,Prednisolone, Favipiravir, Amphotericin B and Apixaban at chemist shops in variouslocations on every Monday. This is being shared with Department ofPharmaceuticals/ NPPA for their required intervention, which is being carried out onregular 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 ofevery 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 ofrequired quantum of medicines/medical devices for the management of COVID 19.

REPLY OF THE GOVERNMENT

3.2 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:-

NPPA and CDSCO both are part of Covid Drug Management Committee (CDMC) set up by DoP and they work closely together to ensure availability of adequate medicines and medical devices. NPPA is regularly conducting market surveys through its Price Monitoring and Resource Units (PMRUs) in 21 States/ UTs for COVID Management drugs as well as six medical devices. Similarly, CDSCO is also conducting frequent surveys of 14 drugs and 3 medical devices to assess their availability.

CHAPTER – IV

OBSERVATIONS/RECOMMENDATIONS IN RESPECT OF WHICH REPLIES OF THE GOVERNMENT HAVE NOT BEEN ACCEPTED BY THE COMMITTEE AND REQUIRE REITERATION

RECOMMENDATION No. 8

Nationwide Training Programme for Rational Use of COVID treating medicines

4.1 With regard to the Nationwide Training Programme for Rational Use of COVID treating medicines, the Committee had recommended as follows:-

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 'Advisoryon 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 DrugCommittee (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 physiciansperiodically to ensure rational and judicious use of Remdesivir. Standard treatment guidelines have also been disseminated through MoHFW's Center of Excellenceinitiative 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 subgroup 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.

REPLY OF THE GOVERNMENT

4.2 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:-

MoH&FW had issued a separate 'Advisory on rational use of Remdesivir for COVID-19 treatment' on 7th June 2021, which was hosted on its website for wider dissemination. Further noting 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 (DGHS). Standard treatment guidelines were also disseminated through MoHFW's Center 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.

COMMENTS OF THE COMMITTEE
(Please see Para No. 1.7 of Chapter - I of the Report)

RECOMMENDATION No. 9

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

4.3 With regard to the Prompt Action Against Hoarding/Black Marketing/Over Pricing of Medicines and Medical Devices, the Committee had recommended as follows:-

(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.

REPLY OF THE GOVERNMENT

4.4 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:-

(a) and (b):Action is initiated by NPPA, under aegis of DoP, on any case that is reported of overpricing in the case of medicines and medical devices as per the provisions of DPCO, 2013. So far as cases of hoarding and black-marketing are concerned, the then Chairman, NPPA vide her D.O. letter dated 23rd April 2021 had requested DCGI to take strict measures for prevention of black-marketing and hoarding of essential drugs. State level team formation has also been urged for field level action monitoring. NPPA has also written a DO letter on 8th April, 2021 to all the State Drug Controllers to closely monitor the production and availability of COVID 19 drugs, prevent black-marketing and hoarding, and ensure availability of life saving essential drugs.

In addition, various regulatory actions were taken by CDSCO against hoarding/black marketing/over pricing of medicines and medical devices related to COVID-19, which are detailed as under:

i. To ensure availability of Covid drugs in the country, CDSCO has requested all State/UT Drugs Controllers to take all proactive steps, i.e., monitoring stockpiling, maintaining checks on availability of drugs, random market survey of critical drugs for used in COVID- 19.

ii. All the States/UTs Drugs Controllers were requested to take necessary steps to expedite issuance of permissions/approvals for manufacturing and issuance of other approvals so that supply chain is not affected.

iii. Based on the complaint received from MoH&FW, regarding shortage of Remdesivir injection in certain areas in Madhya Pradesh (Bhopal, Indore, Gwalior), Gujarat (Ahmedabad, Surat, Rajkot) and Maharashtra (Mumbai, Thane, Ambernath). CDSCO wrote to all State / UT Drugs Controllers requesting to initiate immediate remedial action to ensure supply of Remdesivir injection to public and private hospitals and also to instruct their enforcement officials to keep continuous monitoring on the situation and keep strict vigil on the matter.

iv. CDSCO has requested to all State / UT Drugs Controllers to instruct their enforcement staff immediately to keep strict vigil especially at sensitive places and to

take stringent action against hoarding/black marketing/overcharging for Remdesivir by conducting special drive of monitoring and investigation, so that such incidence could be prevented.

v. CDSCO also requested all State / UT Drugs Controllers to forward information in the given format on a daily basis with regard to enforcement activities to prevent hoarding/black marketing /overcharging / overpricing in respect of Remdesivir, Tocilizumab, Favipiravir and Oxygen Cylinder.

vi. With reports on black marketing/hoarding of COVID related drugs, CDSCO has requested all State/UT Drugs Controllers to instruct their enforcement staff to keep strict vigil on the matter especially at sensitive places and to take stringent action against hoarding/black marketing/overcharging of drugs by conducting special drive of monitoring and investigation, so that any such incident of drugs is prevented. It was also stated that there shall be zero tolerance for any kind of hoarding/black-marketing/overcharging of drugs. It was requested to establish a special task force for the purpose and also nominate a nodal officer in their respective States and UTs to attend to all complainants and intelligence inputs. CDSCO carried out a weekly availability survey of 17 drugs/ devices/ items near Covid designated hospitals and general chemist shops. Its frequency was increased to twice a week when required.

COMMENTS OF THE COMMITTEE
(Please see Para No. 1.10 of Chapter - I of the Report)

RECOMMENDATION No. 10

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

4.5 With regard to the Effective price control of Non-schedule COVID-19 related Medicines and Medical Devices, the Committee had recommended as follows:-

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 ofthe 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.

REPLY OF THE GOVERNMENT

4.6 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:-

Based on the principles laid down in the National Pharmaceuticals Pricing Policy, 2012 (NPPP, 2012), the government has issued the Drugs Prices Control Order, 2013 (DPCO, 2013). The medicines included in the National list of Essential Medicines (NLEM) issued by the MoH&FW are included in the Schedule-I of DPCO, 2013. While the ceiling prices of Scheduled formulations are fixed by NPPA under DoP, in respect of other medicines (non-scheduled), NPPA ensures that their MRP is not increased by more than ten percent of what was prevalent during the preceding twelve months. Price control of non-scheduled medicines will entail revision of NPPP, 2012 and DPCO, 2013.

COMMENTS OF THE COMMITTEE
(Please see Para No. 1.13 of Chapter - I of the Report)

RECOMMENDATION No. 19

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

4.7 With regard to the exemption of Basic Customs Duty and GST on medicines and medical devices for fighting COVID 19, the Committee had recommended as follows:-

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.

REPLY OF THE GOVERNMENT

4.8 In reply to the above recommendation of the Committee, the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has stated as follows:-

Department of Revenue, Ministry of Finance has provided inputs regarding exemption of Basic Customs Duty and GST on medicines and medical devices for fighting COVID 19, as below. While **Table A** shows the list of items that were provided exemption from Basic Customs Duty, the notifications under which the exemptions were provided and the validity of the notifications, the **Table B** shows the exemption from GST and reduction in GST rates provided for COVID-19 related relief goods, the notifications under which the exemptions were provided and the validity of the notifications.

TABLE A **Full Exemption from Basic Customs Duty on import of COVID 19 relief goods**

S.No.	Description of goods	Valid till	Reference
1.	Face Mask and Surgical Mask	30th September, 2020	Notification No. 20/2020-Customs dated 9th April, 2020
2.	Personal protective Equipment (PPE)		
3.	Covid-19 Testing Kits		
4.	Remdesivir Active Pharmaceutical Ingredients (API)	31.10.2021	Notification No. 27/2021-Customs dated 20.04.21, as amended *vide* notification No. 29/2021-Customs dated 30.04.21
5.	Beta Cyclodextrin (SBEBCD) used in manufacture of Remdesivir, subject to the condition that the importer follows the procedure set out in the Customs (Import of Goods at Concessional Rate of Duty) Rules, 2017.	31.10.2021	

6.	Injection Remdesivir.	31.10.2021	
7.	Inflammatory Diagnostic (marker) kits, namely- IL6, D-Dimer, CRP(C-Reactive Protein), LDH (Lactate De-Hydrogenase), Ferritin, Pro Calcitonin (PCT) and blood gas reagents	31.10.2021	
8.	Medical Oxygen	31.08.2021	Notification No. 28/2021-Customs dated 24.04.21, as amended *vide* notification No. 31/2021-Customs dated 31.05.21[#]
9.	Oxygen concentrator including flow meter, regulator, connectors and tubings.	31.08.2021	
10.	Vacuum Pressure Swing Absorption (VPSA) and Pressure Swing Absorption (PSA) oxygen plants, Cryogenic oxygen Air Separation Units (ASUs) producing liquid/gaseous oxygen.	31.08.2021	
11.	Oxygen canister.	31.08.2021	
12.	Oxygen filling systems.	31.08.2021	
13.	Oxygen storage tanks	31.08.2021	
14.	Oxygen generator	31.08.2021	
15.	ISO containers for Shipping Oxygen	31.08.2021	
16.	Cryogenic road transport tanks for Oxygen	31.08.2021	
17.	Oxygen cylinders including cryogenic cylinders and tanks	31.08.2021	
18.	Parts of goods at S.No.6 to 14 above, used in the manufacture of equipment related to the production, transportation, distribution or storage of Oxygen, subject to the condition that the importer follows the procedure set out in the Customs (Import of Goods at Concessional Rate of Duty) Rules, 2017.	31.08.2021	
19.	Any other device from which oxygen can be generated	31.08.2021	
20.	Ventilators, including ventilator with compressors; all accessories and tubings; humidifiers; viral filters (should be able to function as high flow device and come with	31.08.2021	

	nasal canula).		
21.	High flow nasal canula device with all attachments; nasal canula for use with the device.	31.08.2021	
22.	Helmets for use with non-invasive ventilation.	31.08.2021	
23.	Non-invasive ventilation oronasal masks for ICU ventilators.	31.08.2021	
24.	Non-invasive ventilation nasal masks for ICU ventilators.	31.08.2021	
25.	COVID-19 vaccine.	31.08.2021	
26.	Amphotericin B	31.08.2021	
27.	Full exemption from Basic Customs Duty on 6 specified API/ excipients for manufacturing Amphotericin B	31.08.2021	Notification No. 35/2021-Customs dated 12th July, 2021
28.	Full exemption from Basic Customs Duty on Raw materials for manufacturing COVID test kits	30.09.202	

TABLE B Exemption/ Reduction in GST/ IGST on import of COVID-19 relief goods

S.No.	Description of goods	Reduced GST rate	Valid till	Reference
1.	All goods covered under Customs notification 27/2201 and 28/2021 (listed in Table 1 above), imported by State Government or agency authorised by it, free of cost for free distribution.	Nil	31.08.2021	Ad hoc exemption Order (AEO) No. 4/2021-Customs dated 03.05.2021, as amended by AEO No. 5/2021-Customs dated 31.05.2021
2.	All goods covered under Customs notifications 27/2201 and 28/2021 (listed in Table 1 above), imported and donated to Central/ State Government or relief agency recommended by State Government, for free distribution.	Nil	31.08.2021	Notification No. 32/2021-Customs dated 31.05.2021
3.	Medical Grade Oxygen	5%	30.09.2021	Notification No. 05/2021-Central Tax (Rate) dated 14.06.2021
4.	Tocilizumab	Nil	30.09.2021	
5.	Amphotericin B	Nil	30.09.2021	
6.	Remdesivir	5%	30.09.2021	
7.	Heparin (anti-coagulant)	5%	30.09.2021	

S.No.	Description of goods	Reduced GST rate	Valid till	Reference
8.	Covid-19 testing kits	5%	30.09.2021	
9.	Inflammatory Diagnostic (marker) kits, namely- IL6, D-Dimer, CRP (C-Reactive Protein), LDH (Lactate De-Hydrogenase), Ferritin, Pro Calcitonin (PCT) and blood gas reagents.	5%	30.09.2021	
10.	Hand Sanitizer	5%	30.09.2021	
11.	Helmets for use with non-invasive ventilation	5%	30.09.2021	
12.	Gas/Electric/other furnaces for crematorium	5%	30.09.2021	
13.	Pulse Oximeter	5%	30.09.2021	
14.	High flow nasal canula device	5%	30.09.2021	
15.	Oxygen Concentrator/ generator	5%	30.09.2021	
16.	Ventilators	5%	30.09.2021	
17.	BiPAP Machine	5%	30.09.2021	
18.	Non-invasive ventilation nasal or oronasal masks for ICU ventilators Canula for use with ventilators	5%	30.09.2021	
19.	Temperature check equipment	5%	30.09.2021	
20.	Ambulance	12%	30.09.2021	

COMMENTS OF THE COMMITTEE
(Please see Para No. 1.16 of Chapter - I of the Report)

CHAPTER – V

OBSERVATIONS/RECOMMENDATIONS IN RESPECT OF WHICH REPLIES OF THE GOVERNMENT ARE STILL AWAITED

NIL

New Delhi;
08 August, 2022
13 Sravana 1944 (Saka)

KANIMOZHI KARUNANIDHI
Chairperson,
Standing Committee on
Chemicals & Fertilizers.

APPENDIX-I

STANDING COMMITTEE ON CHEMICALS & FERTILIZERS

(2021-22)

Minutes of the Ninth Sitting of the Committee

The Committee sat on Thursday, the 04th August, 2022 from 1500 hrs. to 1645 hrs. in Committee Room 'C', Parliament House Annexe, New Delhi.

PRESENT

Smt. Kanimozhi Karunanidhi, Chairperson

Lok Sabha

2. Shri Ramakant Bhargarva
3. Shri Rajeshbhai Naranbhai Chudasama
4. Shri Ramesh Chandappa Jigajinagi
5. Shri Kripanath Mallah
6. Shri Satyadev Pachauri
7. Dr. M. K. Vishnu Prasad
8. Shri Arun Kumar Sagar
9. Shri Indra Hang Subba

Rajya Sabha

10. Shri Ayodhya Rami Reddy Alla
11. Dr. Anil Jain
12. Shri Arun Singh
13. Shri Vijay Pal Singh Tomar
14. Shri K. Vanlalvena

SECRETARIAT

1. Shri Vinay Kumar Mohan - Joint Secretary

2. Shri Nabin Kumar Jha - Director
3. Shri Kulvinder Singh - Deputy Secretary
4. Shri Panna Lal - Under Secretary

XXX XXX XXX

2. At the outset, the Chairperson welcomed the Members to the sitting of the Committee, convened for consideration and adoption of the following Draft Action Taken Reports:

i. Thirty-Fifth Report on Action Taken by the Government on the observations/recommendations contained in the Thirty-First Report (17th Lok Sabha) on 'Availability of Medicines & Medical devices for COVID Management' of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals).
ii. XXX XXX XXX
iii. XXX XXX XXX
iv. XXX XXX XXX

3. Giving an overview of the important Observations/ Recommendations contained in the Draft Reports, the Chairperson solicited the views/ suggestions of the Members.

4. The Committee, then, took up the Draft Action Taken Reports one by one for consideration and after some discussions adopted them.

5. The Committee then authorized the Chairperson to finalise the Action Taken Reports and present the same to the Parliament.

XXX Not related

Appendix – II

(*Vide* Para 3 of the Introduction)

ANALYSIS OF ACTION TAKEN BY THE GOVERNMENT ON THE RECOMMENDATIONS CONTAINED IN THE THIRTY-FIRST REPORT (SEVENTEENTH LOK SABHA) OF THE STANDING COMMITTEE ON CHEMICALS & FERTILIZERS ON THE SUBJECT 'AVAILABILITY OF MEDICINES & MEDICAL DEVICES FOR COVID MANAGEMENT' OF THE MINISTRY OF CHEMICALS AND FERTILIZERS (DEPARTMENT OF PHARMACEUTICALS)

I	Total No. of Recommendations	19
II	Observations / Recommendations which have been accepted by the Government: (*Vide* Recommendation Nos. 1,2,3,4,5,9,11,12,13,14,15,16,17,18)	14
	Percentage of Total	74%
III	Observations / Recommendations which the Committee do not desire to pursue in view of the Government's reply:- (*Vide* Recommendation Nos.6)	1
	Percentage of Total	5%
IV	Observations / Recommendations in respect of which reply of the Government have not been accepted by the Committee and which require reiteration:- (*Vide* Recommendation No. 7,8,10,19)	4
	Percentage of Total	21%
V	Observations / Recommendations in respect of which final replies of the Government are still awaited: Nil	0
	Percentage of Total	100.0%