

**IN THE SUPREME COURT OF INDIA
CIVIL ORIGINAL JURISDICTION
SUO MOTO WRIT PETITION (C) NO.3/2021**

IN THE MATTER OF:-

**IN RE : DISTRIBUTION OF ESSENTIAL SUPPLIES
AND SERVICES DURING PANDEMIC**

AFFIDAVIT DATED 09.05.2021
ON BEHALF OF THE UNION OF INDIA

**PAPER-BOOK
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ADVOCATE FOR THE UNION OF INDIA: B.V.BALARAMDAS

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FURTHER AFFIDAVIT DATED 09.05.2021
ON BEHALF OF THE UNION OF INDIA

I, Govind Mohan s/o Late Shri Prem Mohan, aged about 55 years, working as Additional Secretary, in the Ministry of Home Affairs, the deponent herein, do hereby solemnly affirm and state on oath as under:-

1. That I am working as Additional Secretary in the Ministry of Home Affairs, Union of India. I state that I am filing the present affidavit in compliance on the basis of the instructions received by me from the Senior most [Secretary, Additional Secretary and Joint Secretary level officer] of the other Ministries of Government of India, namely:- Ministry of Health and Family Welfare, Department for Promotion of Industry and Internal Trade, Ministry of Commerce, Department of

Pharmaceuticals, Ministry of Chemicals and Fertilizers; Ministry of Road Transport and Highways; and Ministry of Railways who as per the transaction of business rules are allotted to respond to and implement the directions pertaining to respective issues which are the subject matter of the present matter. I say that I am competent to consolidate the facts and submission received from various ministries and swear the present Affidavit on behalf of Union of India placing on record the facts received by me from the aforesaid ministries during the course of official communication.

2. It is submitted that, the present Affidavit is being filed in compliance with the order of this Hon'ble court dated April 30, 2021 in Suo Moto Writ Petition (C) No. 3 of 2021.

3. In the aforementioned detailed judgment, this Hon'ble court was pleased to issue several directions for the consideration of the Union of India to deal with the second wave of pandemic. A copy of the judgment passed by this Hon'ble court

in SMWP(C) No. 3 of 2021 dated 30th April, 2021 is annexed herewith and marked as “**ANNEXURE R/1**”.

4. That, the present Deponent shall submit before this Hon'ble court, the steps taken by the Union of India in compliance with the aforesaid Judgment in the following paragraphs.

NATIONAL POLICY FOR ADMISSION IN HOSPITALS

5. It is submitted that, the Ministry of Health and Family Welfare (“**MoHFW**”) enunciated and already intimated all State Governments regarding a policy of setting up three tier Health infrastructure for appropriate management of suspect/confirmed COVID-19 cases. The guidance document issued in this regard on 7th April 2020, envisages/mandates setting up of :

5.1 COVID Care Centre (“**CCC**”) that shall offer care for mild cases. These have been set up in hostels, hotels, schools, stadiums, lodges etc., both public and private. Functional hospitals like Community Health Center (“**CHCs**”), etc,

which may be handling regular, non-COVID cases may also be designated as COVID Care Centers as a last resort.

- 5.2 Dedicated COVID Health Centre (“**DCHC**”) that shall offer care for all cases that have been clinically assigned as moderate. These should either be a full hospital or a separate block in a hospital with preferably separate entry/exit/zoning. Private hospitals may also be designated as COVID Dedicated Health Centres. These hospitals would have beds with assured Oxygen support.
- 5.3 Dedicated COVID Hospital (“**DCH**”) that shall offer comprehensive care primarily for those who have been clinically assigned as severe. These Hospitals should either be a full hospital or a separate block in a hospital with preferably separate entry/exit. Private hospitals may also be designated as COVID Dedicated Hospitals. These hospitals would have fully equipped ICUs, Ventilators and beds with assured Oxygen support.

6. It is submitted that the Central Government has also directed that the Hospitals under the Central government, State Governments and Union territory administrations including private hospitals (in States and Union Territories) managing COVID patients shall ensure the following:

- 6.1** Requirement of a positive test for COVID-19 virus is not mandatory for admission to a COVID health facility if clinically hospitalisation is necessary otherwise. A suspect case shall be admitted to the suspect ward of CCC, DCHC or DHC as the case may be.
- 6.2** No Patient will be refused services on any count. This includes medications such as oxygen or essential drugs even if the patient belongs to a different city.
- 6.3** No patient shall be refused admission on the ground that he / she is not able to produce a valid identity card that does not belong to the city where the hospital is located.

6.4 Admissions to hospital must be based on need. It should be ensured that beds are not occupied by persons who do not need hospitalization. Further, the discharge should be strictly in accordance with the revised discharge policy available at <https://www.mohfw.gov.in/pdf/ReviseddischargePolicyforCOVID19.pdf>. A copy of the letter dated 3rd May 2021 from Government of India, Ministry of Health and Family Welfare, written to Additional Chief Secretary/Principal Secretary Health/Medical education of All States/UTs, giving details of the National Admission Policy, along with the Guidance document on appropriate management of suspect/confirmed cases of COVID-19 and Guidelines Revised Discharge Policy by Ministry of Health & Family Welfare is attached herewith and marked as “ANNEXURE R/2”.

6.5 The Chief Secretaries of States/Union territories have been requested to issue circulars, incorporating the above

directions within three days, which shall be in force till replaced by an appropriate uniform policy.

6.6 It is further submitted that Government of India, Ministry of Health and Family Welfare, has written to all the Additional Chief Secretary/Principal Secretary Health/Medical education of All States/UTs, providing for extraordinary measures to augment the need of medical staff in the country. In view of the need for increasing the availability of trained human resources to tackle the Covid-19 pandemic situation, the following Guidelines/directions are issued in consultation with the National Medical Commission and the Indian Nursing Council:

I - RELAXATION/FACILITATION/EXTENSION

“1. Considering the current situation in the wake of resurgence of COVID – 19, National Eligibility cum Entrance Test-NEET (PG) – 2021 is being postponed. This Exam will not be held before 31st August 2021. At least one-month time will be given after the announcement of the Examination before it is conducted. The State/UT Governments are to make all efforts to reach out to each such prospective NEET candidate and persuade them to

join the Covid – 19 workforce in this hour of need. The services of these MBBS doctors can be utilized in the management of COVID – 19.

- 2. The State/UT Governments may deploy Medical Interns in Covid Management duties under the supervision of their faculty, as part of the Internship rotation.*
- 3. The services of Final Year MBBS students can be utilized for providing services like teleconsultation and monitoring of mild Covid cases after due orientation by and supervision of Faculty.*
- 4. The services of Final Year PG Students (broad as well as super-specialities) as residents may continue to be utilized until fresh batches of PG Students have joined. Likewise, the services of the senior residents / registrars may continue to be utilized until new recruitments are made.*
- 5. B.Sc./GNM Qualified Nurses may be utilized in full-time Covid nursing duties in ICU, etc., under the supervision of Senior Doctors and Nurses.*
- 6. Final Year GNM or B.Sc. (Nursing) students awaiting Final Exam may be given full time Covid Nursing duties at Government/Private facilities under the supervision of Senior File No.Z.20015/43/2021-ME-1 Faculty.*
- 7. The services of Allied Health Care professionals may be utilized for assistance in Covid Management, based on their training and certification.*

8. *The additional human resources thus mobilized should be used only in facilities managing Covid.*

II – INCENTIVES/ RECOGNITION OF SERVICE

9. *Health is a State subject and human resources for health are largely engaged by State Governments. The Central Government engages for their own institutions. The private sector also engages a large number of Health professionals.*

10. *The relaxation mentioned above, finalized in consultation with the National Medical Commission and the Indian Nursing Council, is to further augment human resources for responding to Covid-19 and should be fully availed by public and private institutions engaged in the effort.*

11. *The National Health Mission (NHM) norm for contractual human resource engagement by States/UTs may be considered for implementation of the above proposed initiative for engaging additional manpower. Flexibility will be available with States to decide on remuneration as in the NHM norms. A suitable honorarium for distinguished Covid Service may also be considered*

12. *The financial incentives/ remuneration shall be available only for those who work for at least 100 days for Covid care.*

13. *All Health professionals thus engaged will be covered under the Insurance Scheme of Government for health workers fighting Covid 19.*

14. *All such professionals who sign up for minimum 100 days of Covid duty and complete it*

successfully will be given the Prime Minister's Distinguished Covid National Service Samman from Government of India.

15. State/UT Governments can provide additional health professionals engaged through this process, to private Covid Hospitals as well in surge areas.

16. State Governments/ UT administrations are to ensure that the medical professionals sought to be engaged in Covid related work are suitably vaccinated.

17. The Central Government recommends to State/UT Governments to consider giving preference in regular Government appointments of Health professionals through the respective Public Service Commission/ other recruitment bodies, for those Health Professionals under this special scheme, who complete a minimum of 100 days of Covid related duty.

18. The State / UT Governments may also expeditiously fill vacant posts of doctors, nurses, File No.Z.20015/43/2021-ME-1 allied healthcare professionals and other healthcare staff in Health and Medical departments through accelerated processes as soon as possible and positively within 45 days through contractual appointments.”

A copy of the letter dated the 3rd May 2021 from Government of India, Ministry of Health and Family Welfare, written to Additional Chief Secretary/Principal Secretary Health/Medical education of All States/UTs,

providing for extraordinary measures to augment the need of medical staff in the country is attached herewith and marked as “**ANNEXURE R/3**”.

It is submitted that depending upon the progress in this direction, the Central Government shall consider other incentives without compromising with the merits which can never be compromised in the field of medicine.

OXYGEN ALLOCATION AND AVAILABILITY

7. So far as contents of para 29, 30 and 31 of the order dated 30.04.2021 are concerned, they relate to oxygen supply and related issues. It is submitted that this Hon'ble Court in SLP (c)11622 of 2021 titled as *Union Of India vs. Rakesh Malhotra*, has been pleased to pass an order dated 6.05.2021 which came to be uploaded yesterday ie 8.05.2021. It is stated that in view of constitution of “*National Task Force*” under para 17 of the said order dated 6.05.2021 and in view of the terms of reference contained in para 24, thereof, the Central Government respectfully defers it's response on the said issues mentioned in

the order of this Hon'ble Court dated 30.04.2021 pertaining generation, availability, procurement, allocation, supply, logistical plans for delivery of oxygen, its delivery by the state to hospitals located within their respective territory and the manner of its administration to the COVID 19 patients etc A copy of the judgment and order dated 06.05.2021 passed in SLP (C) Dy. No. 11622 of 2021 titled as *Union of India vs. Rakesh Malhotra* is annexed hereto and annexed as “**ANNEXURE R/4**”.

VACCINES AND VACCINE PRICING

8. At the outset, the following facts need to be appreciated in light of the fact that for the time in the history, India is conducting its biggest vaccination drive for which the country does not have the luxury of a detailed planning time like other vaccines administrated in past over a period of decades.

9. This drive to vaccinate each and every adult person in the country is completely different from other vaccinations conducted by the country in the past in more than one way.

Earlier, there had been no requirement of an emergency vaccination drive like the sudden emerging situation since 2019 onwards. Secondly, scientists in the field of medicine and vaccination had enough time to develop the vaccine and thereafter, there was enough time to manufacture, distribute and administer, the vaccines.

In the present circumstances, the need for vaccination is emergent and urgent. The vaccines are developed very recently throughout the world and therefore, their production has also started very recently. Another peculiar feature of this vaccination is that the vaccine requires two doses, separated by 4 to 8 weeks. India has embarked upon an ambitious vaccine production and administering efforts on a war footing, keeping in mind the large adult population of our country. Our vaccine strategy is based on the following fundamental and cardinal principles :

- (i) to make every possible effort in augmenting more production of vaccines;

- (ii) commencing the vaccination by first prioritising the vulnerable groups as identified by NEGVAC;
- (iii) to make all possible efforts in procuring vaccines from other countries. It may be kept in mind these efforts of procurement from other countries have their own challenges as, unlike other vaccines in the past, every country of the world needs vaccines for its domestic use at this juncture.
- (iv) to make the vaccination drive is policy driven and not haphazard while maintaining a data base of vaccinated persons for tracking them for the second dose ;
- (v) during the process of vaccination, fundamental protocols for prevention of spread of Covid 19 are scrupulously followed.

10. It is submitted that India started the COVID-19 Vaccination in the country from 16th January, 2021 by initiating the vaccination of Health Care Workers (HCWs). From 2nd of February, 2021, the vaccination was started for Front Line

Workers and simultaneously Vaccination of both the groups continued.

From 1st of March, 2021, the persons in the age group of 60 years and above and also the persons above 45 years of age group with 20 earmarked co-morbidities were prioritized for the vaccination. From 1st April, 2021, all the persons above 45 years and those under 45 years of age with co-morbidities are being covered for COVID-19 vaccination. As stated previously, person from the age of 18 to 44 years are eligible from 1st May 2021.

11. It is submitted that every country in this world has followed a system of prioritization in light of limited availability of vaccines in every country. The NEGVAC identified these priority groups on the following basis: -

- a. The first priority was identified as protecting India's Healthcare & Pandemic Response System since the same forms the bedrock of any nation's capacity to deal with the pandemic.

- b. The second priority was identified as controlling the vulnerability and mortality risk for COVID-19 disease. Pertinently, the analyses of COVID deaths in the country reveals that 54% of all deaths occurred amongst those above 60 years of age, whereas those in 50-59 years of age accounted only for 24% and it is estimated that more than 85% of all deaths occurred in the age group above 45 years.
- c. International Experience- Prioritization criteria from WHO and other countries shows that a step-wise layered approach is advisable. For instance, the UK has taken a step-wise approach for prioritizing for vaccination as UK first vaccinated those who are 80 years of age or above, followed by those above 75 years of age, followed by those over 70 years, and so on. Presently, they have started with more younger population. Likewise, France first covered those above 75 years or older age group, followed by those between 65 – 74 years cohort. Similarly USA started with Health Care Workers and higher age groups first and now COVID -19 Vaccination is available to all adults in USA.

It is evident that when age based criteria is used, a staggered approach has been taken by other countries starting with those with higher age group.

12. It is submitted that India's policy is in consonance with WHO guidelines and International Practice in prioritization of population groups for COVID-19 Vaccination.

13. It is submitted that from 1st May, 2021, a new Liberalized and Accelerated National COVID-19 Vaccination Strategy is implemented after detailed deliberations with domain experts at various levels, in response to repeated suggestions made by the State Governments at the highest level during video-conferences [and also through written communications] emphasising simultaneous vaccination of other groups within the 18-44 age group, analysing the figures of projected availability and projections and as an executive policy keeping in mind the health and safety of citizens as prime consideration balancing it with the available resources of the country. As per the said strategy, vaccine manufacturers would supply 50% of their monthly Central Drug Laboratory (CDL) released doses to

Government of India and would supply remaining 50% doses to “other than Government of India channel” i.e. State Governments, Private Hospitals and Hospitals of Industrial Establishments. Under this Strategy, Vaccination other groups between the age of 18 to 44 years is now permitted under other than Government of India Channel.

14. It is critical to note that under the new strategy, the vaccination effort of the Government of India will continue to serve the priority group identified by NEGVAC, i.e. those above 45 years of age and persons with comorbidities under 45 years of age. This priority group continues to remain the primary target for the Central Government as advised by experts and as per the practice followed globally and all efforts will be made to vaccinate this priority group at the earliest. It is with a view to respect the wishes of various State Governments, that vaccination has simultaneously started amongst the population groups between the age of 18-44 years.

15. It is submitted that under the new policy, the vaccine manufacturers would, in a transparent manner proactively

make an advance declaration of the price for 50% supply that would be available to State Governments and Private Hospitals/Hospitals of Industrial Establishments before 1st May, 2021. The price for the Central Government vaccination is already fixed and declared.

16. It is submitted that based on the monthly production of vaccine manufacturers and CDL cleared doses projected to be available with them, the quantity of doses available for “Other than Government of India Channel” was worked out on State-wise population of 18 to 44 years “pro-rata”. It is submitted that though the States are procuring the vaccines from the manufacturers, the Central Government has, in consultation with the vaccine manufacturers determined the pro-rata population of each State in the age group of 18-44 and each State will procure only that quantity so that there is no disparity in availability of vaccines between the States inter-se either based upon difference in their bargaining power or otherwise. Each State is informed by the Central Government in writing about the number of vaccines it would receive for the month of May.

2021, from the manufacturers which would be the figure of pro-rata number of State's population which belong to 18-44 years age group. A copy the list containing the figure of vaccine doses calculated from government of India allocation for people 45 and above and a copy the list containing the figure of vaccine doses calculated based on *pro-rata* population of each State for the above purpose falling within 18-44 years age group for the month of May is annexed herewith and is marked as "**ANNEXURE R/5**". It is submitted that the said figures of each State are individually informed in every State.

This exercise is absolutely essential and this discipline is mandatory so as to have uniform vaccination throughout the country. This historical endeavour can be successful only by treating India as one unit and considering the question on pan-India basis. This can be achieved only with each State following the discipline in letter and spirit, to be in tune with simultaneous vaccination of the country avoiding any demands by one State at the cost of other States and residents of the rest of the country.

17. It is submitted that though under the new vaccine strategy, it is for each State Government to procure the vaccines as stated above, the Central Government has, by conducting informal consultations with the vaccine manufacturers, ensured that the prices of vaccine is uniform for all the States so as to avoid any disparity resulting from one State ending up buying vaccine at a higher price than the other.

18. It is also submitted that citizens of 18 to 44 years are getting vaccination free of cost as all the State Governments have announced free vaccination for this population group of 18-44 years. Thus, all citizens of all age groups will get free vaccination throughout the country.

19. It is submitted apart from the above, the States have also been provided the information of the total number of doses of both vaccines available to States and UTs from “Government of India channel” for the identified priority groups [health care workers, frontline workers and population above 45 years of age] free of cost from 1st May, 2021 to 15th may, 2021. This data

would be released every fortnight to each of the State Governments.

20. It is submitted that against this approval from DCGI, Dr Reddy's Laboratories has imported the first consignment of 1.5 lakh doses. It is submitted that the Central Government is in active discussions with Pfizer, Moderna, J&J and other vaccine developers/manufacturers outside India to facilitate their imports. It is submitted that if these efforts are successful, it will make more quantity of vaccines available for the country and thereby lead to increased pace of vaccination.

21. So far as the part of the order dated 30.04.2021, passed by this Hon'ble Court with respect to "Vaccine and Immunisation" is concerned, the following facts are placed on record to satisfy this Hon'ble Court that the Central Government has taken its executive policy decisions in the most scientific manner, in consultation with experts in the field, keeping in mind the health and well-being of the citizens as the main and only focal point in the context of the unprecedented human crisis faced by

the nation requiring no second guessing as there are several factors put in to such decision making for effective pandemic management for which there may not be existing any judicially manageable standards. It is most respectfully submitted that in the times of such grave and unprecedented crisis which the nation is fighting the disaster of an unprecedented magnitude, the executive functioning of the government needs discretion to formulate policy in larger interest. It is submitted that in view of the unprecedented and peculiar circumstances under which vaccination drive is devised as an executive policy, the wisdom of the executive should be trusted.

22. As pointed out hereinabove, the vaccine procurement and immunization process is devised so as to ensure :

- (i) Equitable distribution of vaccines to the population based upon their age and vulnerability, arising both from age and co-morbidities;
- (ii) The marginalized section of the society is taken care of adequately;

- (iii) The distribution of the vaccine amongst the States is based on equitable and rational criteria to eliminate any possibility of difference in bargaining power of one State and have a detrimental impact on the resident of the other State;
- (iv) By adopting consultative process and discussing at the highest possible level with the existing manufacturers of two vaccines, it is ensured that the pricing of vaccine is also not only reasonable but uniform throughout the country removing any possibility of one citizen in one State getting the vaccine at a higher price as compared to a similarly situated resident residing in another State.
- (v) Due to consultations and “persuasion” by the Central Government both the manufacturers of vaccine, Bharat Biotech and SII, have declared their respective prices which are uniform for all State Governments. It is pertinent to note that the Central Government by nature of its large vaccination programme, places large purchase orders for vaccines as opposed to the State Governments

and/or Private Hospitals and therefore, this reality has some reflection in the prices negotiated.

It is however submitted that this price factor will not have any impact on the ultimate beneficiary namely, the eligible person getting the vaccine since all State Governments have already declared their policy decision that each State will be administering vaccine to its residents, free of cost.

Thus, while it is ensured that the two vaccine manufacturers, are not unduly enriched from out of public money, the citizens are not supposed to make any payment for getting both dose of the vaccine.

- (vi) It is submitted that vaccination being utmost priority of the Central Government, all executive decisions are taken keeping the said priority in mind. It is a fact which cannot be disputed that till date there are only vaccines available from two vaccine manufacturers. Both manufacturers [one an Indian company and second a licensee of a British company] have taken financial risk in developing and

manufacturing these vaccines and it is prudent to take decisions on pricing through a negotiations in a transparent consultative process keeping statutory provisions as a last resort under the present circumstances.

- (vii) With a view to ensure that there is no disparity between the States inter-se, with active consultation of the Central Government with both the manufacturers, the Central Government has successfully fixed uniform price to be paid by all the State Governments.

At this juncture, it is required to be noted that as per the policy [which is devised keeping the priority of maximum vaccine reach to the citizens depending upon their vulnerability in mind, ensuring equitable distribution of quantity of vaccine to all States at a uniform rate, the possibility of vaccine pricing decision in India having an inevitable impact on the country's efforts bringing in more global vaccine manufacturers in to India], the policy mandates 50% of total manufactured quantity of

vaccine from both manufacturers to be supplied to the Central Government [the logic being to give priority in vaccination to the most vulnerable group of the population] and the remaining quantity to be uniformly distributed amongst all States on a pro rata basis [viz. the total manufactured quantity from both the companies is divided and allocated to the States keeping in mind the total population of each State between the age group of 18-44 years]. Out of the 50% quota allotted to each State, the division is made on 50%/50% basis. In other words, from out of the 50% allotted to the State, 50% will go to the State [calculated on pro-rata basis based upon the population of age group of 18-44 years] and the balance 50% will go to the private sector based upon the contracts between private sector and vaccine manufacturers.

Those who choose to be vaccinated and can pay the price, can go to private hospitals. Vaccination through private sector of 25% quantity, would facilitate better access and will reduce the operational stress on the

government vaccination facilities as those who can afford to pay and prefer to go to a private hospital, would not come to government vaccination facilities reducing the crowd which can continue to serve the rest. It is however submitted that this allocation, found to be more prudent, may undergo a rational change if, on facts, as per their respective performance and availability of vaccines. This policy and process is dynamic to factor in some changes in public interest in future, either in the event of more doses being available from within India or from outside or for any other reason, if such change is required.

(viii) It is submitted that as per medical advice and global policy, it is settled across the world that the age group above 45 years is especially vulnerable to COVID 19. In light of the same, it has been decided that the vaccination of this group [above 45 years] is absolutely imperative. Since, the vaccination of the entire country is not possible in one stretch due to the very suddenness of the pandemic,

limited availability of vaccine doses and the vulnerability as the prime consideration, the policy is framed as above which is just, equitable, non-discriminatory and based upon an intelligible differentiating factor between the two age groups. This policy thus, conforms to mandate of Article 14 and Article 21 of the Constitution of India and is made after several rounds of consultation and discussion with experts, State Government and vaccine manufacturers requiring no interference by this Hon'ble Court as while dealing with a pandemic of this magnitude, the Executive does have a room for free play in the joints, in larger public interest.

It is submitted that efforts in the direction of procurement of other vaccines from other countries is essentially a responsibility of the Central Government. For such procurement, significant efforts are being made at several levels, including through diplomatic channels, both within and outside the country. If and when such

procurement takes place, the aforesaid system of distribution may undergo a fresh look.

23. It is submitted that as already explained, the COVID vaccine strategy of the UOI is formulated to address immediate, medium term and long term perspectives. On an immediate front, the availability, augmentation and enhancement of vaccines and completing vaccination of vulnerable groups is the topmost priority of the Nation. While pricing of vaccines is an important medium to long term issue for India, for which the UOI is making all out efforts on multiple platitudes (illustrated in the earlier 2 affidavits of the UOI), on National as well as International arena. On the advice of experts, the current strategy is to focus on priority areas of vaccination and to allow enhanced production and further research and development to continue and expand with full potential without any real or perceived constrictions. Sometimes, steps that are taken for immediate needs, to tide over an imminent crisis, may turn out to be imprudent in a long run. However, they need to be appreciated, understood and acknowledged, keeping in mind the

complete strategy and policy and holistic picture of immediate, medium and long term needs, while also retaining the capacity to remain dynamic to deal with an ever mutating virus, whose exact graph cannot be predicted with accuracy and continuous upgradation of knowledge pool with further experience and research.

24. It is the respectful submission of the Central Government that while Central Government is duty bound to fully assist this Hon'ble Court, while this Court looks into the steps taken on National, Regional and grassroot levels for management of this global pandemic and its waves/surges, propelled by mutated versions of the virus, the policy, strategy and steps taken by the executive, based on expert medical and scientific advice, have to be appreciated in the context of a medical crisis and as the decisions are taken after detailed deliberations at the highest executive level, for germane reasons, no interference is called for in judicial proceedings, leaving it open for the executive to discharge its executive functions in larger interest.

25. In a plethora of judgements, this Hon'ble Court has laid down the parameters for judicial review of executive policies, which can only be struck down or interfered with on the grounds of manifest arbitrariness, allowing sufficient play in the joints to the executive, to function in accordance with its Constitutional mandate. In the context of a global pandemic, where the response and strategy of the nation is completely driven by expert medical and scientific opinion, there is even little room for judicial interference. Any overzealous, though well-meaning judicial intervention may lead to unforeseen and unintended consequences, in absence of any expert advice or administrative experience, leaving the doctors, scientists, experts and executive very little room to find innovative solutions on the go.

26. At this juncture, it is reiterated that during the ongoing consultation with the States, demands/concerns were raised by the various State Governments to expand the scope of vaccination drive to include the beneficiaries beyond the priority groups identified by National Expert Group on Vaccine

Administration for COVID 19 (“**NEGVAC**”) as approved by Central Government [healthcare workers, frontline workers and population above 45 years of age]. Further, to meet the aspirations of the States for expanding vaccination drives to other groups between the age of 18-44 years and to effectively manage the vaccination drive, the vaccine procurement was also decentralized, while taking care that no disparity arises as stated above.

However, since the priority group as identified by the Union of India (which is considered more vulnerable globally) was not fully vaccinated, it was considered imperative to carry out two drives separately i.e., in a decentralized manner to achieve higher efficiency and reach. It is submitted that, in the last four months, India has built significant capacity at the state and local level to plan and execute large scale vaccination drive.

27. It is submitted that with regard to vaccination, the Court had posed certain queries to the Central Government to ensure the protection of fundamental rights of all citizens, who will be

eligible to take the vaccine from 1st May, 2021. The following were the queries:

“37 Besides the above issues, the Central Government is directed to clarify the following issues in order to ensure the protection of the fundamental rights to equality and to life and personal liberty for all persons who will be eligible to take the vaccine from 1 May 2021:

- (i) Whether the Central and State Governments have introduced any initiatives for ensuring the immunization of persons who do not have access to digital resources as otherwise the mandatory requirement of registration over the Co-WIN digital portal for persons in the age group of 18-44 years will deprive a large class of citizens of vaccination;*
- (ii) Since the Central Government commits to vaccinating persons over 45 years, free of cost, in view of their vulnerability, whether walk-in facilities for vaccination will continue for these persons after 1 May 2021;*
- (iii) Whether the Central or State Governments propose to undertake targeted vaccination drives for persons who are providing on-ground assistance during the second wave of the pandemic - such as crematorium workers, who were not considered as Frontline or Healthcare workers for Phase 1 of the vaccination drive;*
- (iv) Whether, and if so what, steps being undertaken by INYAS, the nationwide mass awareness campaign for COVID-19 vaccination, for ensuring outreach in rural areas and socio-economically underprivileged sections*

of society including the possibility of using mobile vans, vehicles and railways to vaccinate such people as well as those living in remote areas, near their doorsteps so as to minimize their travel and potential infection with COVID-2019. Efforts must also be made that a lack of an identity proof does not create a hindrance in the process of immunization of all individuals, specifically, the underprivileged;

(v) Whether the Central government will revisit its policy by procuring 100% of the doses which can then be equitably disbursed to the State Governments; and

(vi) Since the vaccine administration is now to be a shared responsibility of the Union and the States, the Central Government and the State Governments shall provide- (a) a breakup of the current and projected availability of vaccine stocks for the next 6 months; and (b) a timeline for achieving immunization of the newly eligible 59 crore persons who are aged between 18-44 years.

These issues are of vital importance, since vaccination appears to be one of the most important strategies to combat further spread of the pandemic, and would also provide a measure of security and assure the people about their health and well-being.

27.1 It is submitted that with regard to point (i), i.e. providing other modes other than the digital portal, the Central Government places the following facts. The Co-WIN digital portal permits registration of more than one person (at present 4 persons) using the same mobile number.

It is submitted that much of India resides in rural areas which are governed by local self governments at grass root levels like Panchayats. This grassroot level bodies are very successfully representing rural India in all schemes of State Governments as well as Central Government. After the country entered the digital era, almost all these gram panchayats have established common service centres [“CSC”] which have a digital platform to be used by the people. These CSCs and its infrastructure is widely and effectively used in rural areas for various purposes and is found to be an effective module taking the development to the grass root levels. This provides access to the internet to a vast variety of persons who may not be adept in using it or may not have direct access to it.

Further, citizens who do not have access to digital resources can take help from family, friends, NGOs, and

above referred Common Service Centres (CSC), etc., for online registration in Co-WIN.

At present, for vaccination of the 18-44 years age group, only online system of registration & booking is available which is a decision taken keeping in mind several administrative factors and for effective vaccine administration. As evident from above, the doses of vaccine are not unlimited, constraints of production capacities and permitting walk in vaccination/registration is anticipated to result in overcrowding at the vaccination centres, defeating the very purpose of vaccination. Any such overcrowding is effectively avoided due to online registration as different time slots are given in advance to each of the applicant after online registration to ensure that at any given point of time, crowding in the vaccination area is avoided.

There is one more administrative angle which is factored in while deciding the initial vaccination through registration online only. It is submitted that when a

decision is being taken for the entire country, the Central Government has to keep the infrastructural constraints in mind in various parts of the country. Any vaccination centre would require certain minimum requirements like doctors, nurses and other paramedics, and such other things. Over and above the constraint of this human resource, there is obviously going to be a constraint of infrastructural resource as any vaccination centre would need a waiting area big enough to maintain social distancing, an earmarked room where vaccine would be administered and earmarked area where a person vaccinated is required to wait for 30 minutes as per medical protocol which also should be sufficient to ensure social distancing. It is therefore considered in larger interest of health and safety of everyone to be administratively prudent not to permit walk in vaccination and registration for the age group of 18-44 years and employ the use of digital registration for the

above reasons which are germane rational and non-arbitrary requiring no interference.

Later as more vaccines are available and administered under the online system, the system of onsite registration and walk-in vaccination at COVID Vaccination Centres would be considered.

It is humbly submitted that the Union Government has formulated SOP on vaccination of persons without any prescribed identity cards.

A copy of the DO letter dated 23.04.2021 written by Secretary MoH&FW to all the Chief Secretary/Principal Secretary Health of All States/UTs and a copy of the SOP for COVID-19 Vaccination of Person without prescribed Identity Cards through CoWIN is annexed herewith and marked as “ANNEXURE R/6”.

It is submitted that insistence for the identification card has a reasonable nexus and logic. As pointed out above, the vaccination is necessarily linked to the age

group of the person. The seven permissible identity card are not essential for establishing the identity of the individual, but to ascertain the age of the person.

It is further submitted that the country is facing a very peculiar problem in vaccination. Unlike other vaccines, all available vaccines for COVID-19 require two doses to be administered within the prescribed time duration/interval. It is therefore imperative to keep a record of the persons getting vaccinated with the first dose or the second dose, as the case may be, for the purposes of ensuring that the citizen do get both the doses in the prescribed period. The identification through the contact details which includes address, phone number, etc. is used to track the person getting the first dose of the vaccine and issue appropriate reminder/s for the second dose of the vaccine. In absence of such tracking and absence of the second dose being administered to such persons, not only the said person would expose himself but would also result in wasting one dose which the country cannot afford. As a

matter of fact such tracking is being done, ensuring that the person who took first dose comes for the second dose. This is possible only if verifiable details of persons are available from the identity cards.

The said record further strengthens the database available for macro-health planning for the future. This data will also help in informing citizens about any of the needs emerging out of the evolving nature of the pandemic. The Central Government however, is alive to the problem arising from insistence for identification proof. As per the revised SOP, the Central Government has permitted bulk registration of the people of one homogenous group like a village, old age home, prisons, etc., at designated facilities under special vaccination sessions without requiring any of the seven identity card. These sessions will be created by the District Immunization Officer under the guidance of District Task Force. District Task Force may identify such groups of persons in respective district not having any of the prescribed individual Photo ID cards with

assistance from concerned government department/organization like department of minority affairs, social justice, social welfare, etc. This initiative will ensure the immunization of persons who do not have Photo ID and may also do not have access to digital resources.

27.2 It is submitted that with regard to point (ii), Walk-in facilities or On-site registrations for vaccination of persons over 45 years will continue after 1 May 2021. This is possible as the vaccination of this vulnerable group has started since some time and is carried out at separately designated centres since some time. The ground experience in the country shows in this age group and vaccination centre designated for them, the problem of overcrowding etc. is largely not experienced.

27.3 It is submitted that with regard to point (iii) that, Crematorium workers regardless of age, (be they permanent, contractual, outsourced and manpower working with contractor) engaged in working in all

cremation grounds are already included under the priority group of municipal workers under “Frontline workers” category. Similarly, all Panchayat workers in rural areas involved in COVID-19 activities, regardless of age, are also included in “Frontline Workers” category.

27.4 With regard to point (iv) viz. possibility of door to door vaccination [or through mobile vans, railways, vehicles, etc.] the following facts are placed for consideration.

The COVID vaccination is designed to be provided only at identified COVID vaccination Centres, both Govt and Private, registered on COWIN software for good, germane and rational reasons.

There are four key requirements to create COVID Vaccination Centres (“CVC”) under COVID 19 vaccination programme.

These are availability of :

- (i) adequate space,
- (ii) adequate cold chain storage facility,

- (iii) adequate number of vaccinators & medical support staff
- (iv) adequate arrangements for management of adverse events following immunization (“AEFI”).

Beneficiaries can book the slots in these identified CVCs through COWIN software based on their residence pin code, for the comfort and convenience of the people, facilitating the vaccination at nearby CVC. It is submitted that it may be difficult to timely address Adverse Event Following Immunization (“AEFI”) in an adequate manner in the situation of a home or vaccination at the door steps.

In case of any adverse event following immunization, case management may not be proper and there will be a delay in reaching health facility, even though ambulances are stationed nearby. It is submitted that maintaining protocol of observation of each and every beneficiary for 30 minutes after vaccination is not possible, as each household may have one or two beneficiaries and it may not be practically

possible for the vaccination team to spend more than 30 minutes in each and every household. This will in fact delay the entire vaccination drive. Further, it may be noted that for administration of vaccine logically the same need to be stored in special “Vaccine Carriers” to maintain the requisite temperature and to further prevent contamination. If the vaccine are administered on a door to door basis, the vaccine carrier box would be required to be opened again and again thereby violating its threshold temperature which is necessary to maintain vaccine efficacy and prevent it from causing AEFI, which may even affect the vaccine confidence and programme performance. It is submitted that, repeated opening of vaccine carrier while giving vaccine at each and every house will expose the vaccine to the temperature beyond recommended range and this may reduce the efficacy of both open and unopened vials kept in the vaccine carrier. Furthermore, there are chances of vaccine wastage due to increased time required visiting door to door for socio-economically and

underprivileged sections. As per the guidelines open vial policy is not applicable for COVID-19 vaccine, which means a vial once opened needs to be discarded after 4 hours. It will take time to reach out to each beneficiary and this may lead to vaccine wastage of open vials used for vaccination. It is submitted that, vaccination at home may expose the healthcare personnel and frontline health workers to undue pressures from community to vaccinate those other than on due list and hence will need additional security cover as well. Furthermore, the vaccinator will be travelling and delivering the vaccine at various locations and will always be at risk of getting COVID-19 infection. Vaccinator will be exposed to multiple household environments as the COVID vaccine cannot be given at door or outside the home. The vaccination team will require siting place at home and would have to spend some time inside the home of the beneficiary. In this regard, recently, the Union Government has formulated SOP on vaccination of persons without any prescribed identity

cards. As per the SOP, facilitated bulk cohort registration would be possible at designated facilities under special vaccination sessions. These sessions will be created by the District Immunization Officer under the guidance of District Task Force. District Task Force may identify such groups of persons in respective district not having any of the prescribed individual Photo ID cards with assistance from concerned government department/ organization like department of minority affairs, social justice, social welfare, etc. This initiative will ensure the immunization of persons who do not have Photo ID and may also do not have access to digital resources. Further, during various meeting, States/ UTs have been requested to undertake mass awareness campaign for COVID Vaccination Programme.

27.5 With regard to point (v), the answer has been already elaborated hereinabove.

27.6 With regard to point (vi), at present the availability of vaccines for next 6 months would be difficult to project as it depends upon the successful augmentation in existing manufacturing capacity of two vaccine manufacturers, the procurement of other vaccines from other countries and its quantity etc. These projections although require a dynamic change due to the very nature of the constraints referred to hereinabove.

It is submitted that the policy formulated by the Central Government is compliant of constitutional principles. The classification has a reasonable nexus and has an intelligible differentia. The policy is made after careful consideration of all relevant factors referred to above by the authority competent to make the policy. It is respectfully submitted that even though some other policy may be suggested and even if the Court finds it to be better, the same may not be a ground for this Hon'ble Court exercising its power of judicial review to substitute the policy more particularly when in such unprecedented

times, the Executive, having access to all relevant information in consultation with all stakeholders and domain experts, must have some free play in the joints based upon on ground experience and in larger public interest.

On the Issue of Ramping up the Immunization Drive in India

28. It is submitted that new ‘Liberalized Pricing and Accelerated National Covid-19 Vaccination Strategy would further ramp up the pace of COVID-19 vaccination.” It aims at liberalized vaccine pricing and scaling up of vaccine coverage to incentivize vaccine manufacturers to rapidly scale up their production and to attract new vaccine manufacturers. It would make pricing, procurement and administration of vaccines more flexible and ensure augmented vaccine production as well as wider availability of vaccines in the country. It is further submitted that, incentivisation of private manufacturers will further lead to more pharmaceutical manufacturers entering

the market and scaling up the production of the vaccines. By this, the vaccines availability can be secured and those who can avail the benefit can do so. Herein, differential pricing is based on the concept of creating an incentivised demand for the private vaccine manufacturers in order to instil a competitive market resulting in higher production of vaccines and market driven affordable prices for the same. This will also attract offshore vaccine manufacturers to enter the country. This will result in increased availability of vaccine.

29. It is further submitted that, the Government of India is consistently working to secure vaccines availability. Two vaccines are currently part of vaccination drive since January 2021. Another COVID-19 vaccine, Sputnik V developed by Gamaleya Institute, Russia and distributed in partnership with Dr. Reddy's Laboratories, has received Emergency Use Authorization by the National Regulator in April 2021 and would be available now. Many other candidates are in the late stages of clinical trials and, therefore, expected to receive

necessary approval that would further increase the availability of vaccines.

30. It is further submitted that, the production capacity of the vaccines under the vaccination drive has been gradually ramped-up and is expected to increase further in the next couple of months:

- Serum Institute of India Ltd. has ramped up production from 5 crore doses / month to 6.5 crore doses per month and further ramp-up is expected by July 2021.
- Bharat Biotech Intl Ltd. Has increased production from 90 lakh/ month to 2 crore doses/ month and further increase is expected upto 5.5 crore doses/month by July 2021.
- Sputnik-V is expected to increase production from 30 lakhs to 1.2 crore doses/month by July 2021.

It is humbly submitted that, new vaccines, as and when approved by the National Regulator, will be taken up under the programme to improve vaccine availability and vaccination coverage. As a new development, in order to speed-up the regulatory process of use of offshore vaccines within the country,

and to accelerate the access to vaccines, the regulatory and testing processes have been simplified. As some foreign vaccines have now been administered globally in large numbers, the NEGVAC has decided to allow the conduct of bridging trials of the foreign vaccines simultaneously with its market deployment as opposed to the earlier requirement of conducting bridging trials prior to market deployment, following due safety and quality protocols and in light of the global experience of these vaccines if such vaccines are approved by USA, UK, EU and WHO. This would enable earlier introduction of foreign vaccines in the programme and would cut-short the time required for in-country bridging trials (nearly 4 months). It is submitted that discussions for procurement of vaccines from out of India has been going on since third-quarter of 2020, at a time when the foreign vaccine manufacturers were prioritizing their domestic requirements. These negotiations are a complex undertaking which is currently ongoing on a war footing using all resources including diplomatic channels. Any discussion on this aspect is

likely to be detrimental to these efforts being made by the Central Government in other countries.

Methodology of Central Government to procure adequate Vaccine doses

31. It is submitted that the Government of India is consistently working to secure vaccines availability as a continuous effort to secure adequate vaccine doses for National COVID-19 Vaccine Programme. The NEGVAC had interactions with vaccine manufacturers in the initial phases of COVID Vaccination programme to secure adequate vaccine doses. For the initial phases, 6.6 crore doses were secured. Herein, the NEGVAC, after comprehensive deliberation, recommended that vaccines for COVID-19, which have been developed & are being manufactured in foreign countries and which have been granted emergency approval for restricted use by United States, European Medical Agency (EU), United Kingdom, Japan or which are listed in WHO (Emergency Use Listing) may be granted emergency use approval in India, mandating the

requirement of post-approval parallel bridging clinical trial, in place of conduct of local clinical trial as per the provisions prescribed under Second Schedule of the New Drugs & Clinical Trials Rules 2019. Herein, the Department of Biotechnology, under the DBT-BIRAC COVID-19 Research Consortium is supporting the research and development of nearly eleven vaccine candidates by industry and public sector laboratories. Three of these vaccine candidates have progressed from Proof-of-Concept to the clinical development stage and are currently undergoing clinical trials. To further accelerate the COVID-19 vaccine development efforts, support for vaccine candidates in clinical development is being provided under “Mission COVID Suraksha the Indian COVID-19 Vaccine Development Mission”. It is also submitted that 100% advance of Rs. 1732.50 cr was released to Serum Institute of India (SII) for 11 crore doses of Covishield vaccine for the months of May, June and July. Additionally, 100% advance of Rs. 787.50 cr was released to Bharat Biotech India Ltd (BBIL) for 05 crore Covaxin doses for the months of May, June and July.

Breakup and Correlation with the total cost of development and production of the two vaccines

32. It is submitted that, financial support to Bharat Biotech International Ltd. (BBIL) and Serum Institute of India Pvt. Ltd. (SIIPL), for the production of Covaxin and Covishield, in the form or advance payment [not support or investment] of Rs. 1732.50 cr was released to Serum Institute of India (SII) for 11 crore doses of Covishield vaccine for the months of May, June and July and similarly, an advance payment of Rs. 787.50 crores was released to Bharat Biotech India Ltd (BBIL) for 05 crore Covaxin doses for the months of May, June and July. The current procurement price of Government of India is based on the price negotiated by the NEGVAC.

Direct and indirect grant/aid provided for research, development and manufacture of all existing vaccines and \future vaccines

33. It is submitted that no governmental aid, assistance or grant is made either for research or development of either Covaxin or Covishield. However, they were given some financial assistance for conducting clinical trials. The details thereof are as under:-

COVAXIN

- COVAXIN has been developed under public private partnership between Indian Council of Medical Research (ICMR) and Bharat Biotech International Ltd. (BBIL).
- The PPP was executed under a formal Memorandum of Understanding (MoU) between ICMR and BBIL which includes a 5% royalty clause for ICMR on net sales and other clauses like prioritisation of in-country supplies.
- The product Intellectual Property rights are shared. It is also agreed that the name of ICMR-National Institute of Virology (NIV) will be printed on the vaccine boxes. The same is being done now.
- ICMR has not provided any funds to BBIL for COVAXIN development. However, funds have been spent in various activities undertaken by ICMR-NIV, Pune for COVAXIN development. Also phase 3 clinical trials of COVAXIN

have been funded by ICMR. The trials have been conducted at 22 sites in 25,800 participants.

- Details of activities undertaken by ICMR/ICMR-NIV are as follows:
 - Isolation of the virus, bulk production of virus and characterization of the vaccine strain at NIV.
 - Preclinical studies of the vaccine strain in hamsters and monkeys.
 - Quality control samples of small animal studies and phase 1 and phase 2 serum samples.
 - Phase 3 clinical trial (full funding).
 - Assessing the effectiveness of COVAXIN against variant strains of SARS-CoV-2 (UK variant, Brazil variant, South African variant and Indian double mutant strain)

Total estimated expenditure of ICMR: 35 crores

COVISHIELD

- The bridging studies of COVISHIELD in 1600 participants in India were supported by ICMR in partnership with Serum Institute of India (SII). No funds were provided to SII. Funds were transferred to 14 clinical trial sites.
- ICMR also supported laboratory studies on characterization of immune response related to

COVISHIELD at ICMR-National AIDS Research Institute (NARI), Pune.

Total estimated expenditure of ICMR: 11 crores

34. It is submitted that, the Department of Biotechnology, under the DBT-BIRAC COVID-19 Research Consortium is intensively supporting the research and development of nearly eleven vaccine candidates by extending financial, technical and research support to industry and public sector laboratories. Three of these vaccine candidates have progressed from Proof-of-Concept to the clinical development stage and are currently undergoing clinical trials. To further accelerate the COVID-19 vaccine development efforts, support for vaccine candidates in clinical development is being provided under “Mission COVID Suraksha the Indian COVID-19 Vaccine Development Mission”. In regard to Sputnik V, upon the directions of National Expert Group on Vaccine Administration for Covid-19 (NEGVAC), Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Undertaking (PSU) of the Department of

Biotechnology has been identified to provide advisory support for clinical trials of Sputnik V in India..

35. It is further submitted that, in accordance with the directives received, efforts have been made to support scale-up production of Covaxin, under Mission COVID Suraksha. Accordingly, support for one private industry and three public sector manufacturing facilities, is under consideration, to make them ready with enhanced capacities to support augmented vaccine production over the next 6-8 months. The vaccine manufacturers recommended for support are Bharat Biotech, Hyderabad; Indian Immunologicals, Hyderabad; Haffkine Biopharmaceuticals, Mumbai; Bharat Immunologicals and Biologicals, Bulandshar. An amount of ~Rs. 200 Cr. has been allocated for supporting augmentation of capacities for manufacturing, whereby, it is expected that the current manufacturing of Covaxin of 10 million doses/ month will be enhanced to nearly 100 million doses/ month in the next 8-10 months. Provision of financial support in the form of grant-in-

aid has been recommended; however, disbursements have yet to be made.

SUPPLY OF ESSENTIAL DRUGS, BLACK MARKETING

Re:- Issue of Compulsory License for Vaccine and essential Drugs (Remdesivir, Tocilizumab)

36. Hon'ble Supreme Court in its order dated 30.4.21 has observed that the Central Government can consider using its powers under Sections 92,100 or 102 of the Patents Act to increase production of essential drugs to ensure that it is commensurate to the demand.

37. Further, Hon'ble Delhi High Court in its order dated 20.04.21 in W.P. (C) 3031/2021 has directed that the Government/Controller should not hesitate to invoke their jurisdiction and powers under the Patent Act, since the lives of thousands of people are being lost each day in the country due to COVID.

38. Director General Health Services, the Technical Head in Ministry of Health and Family Welfare, Government of India has worked out an estimated requirement of 1 crore vials of *Remdesivir* per month in case the situation of new active cases continues at the present level. While the production levels prior to the recent surge in Covid cases was only around 60,000 per day, with the efforts of the Government, have increased to almost three and a half times in a span of three weeks to around 2 lakh per day. To enhance the production capacities of the 07 licensed manufacturers 35 additional manufacturing sites for *Remdesivir* have been approved by DCGI, taking the total number of sites to 57, and monthly manufacturing capacity to 1 crore vials.

39. The Government is also making all efforts to address the supplies of essential inputs, raw materials such as APIs etc. to ensure that the installed capacities are fully utilized. Department of Pharmaceuticals and Ministry of External Affairs are closely supporting sourcing of raw materials to ensure optimum production levels of *Remdesivir* in the Country.

In fact availability of certain inputs is becoming a major constraint in further upscaling the production, rather than addition of the manufacturing capacity.

40. In addition, MoHFW is procuring through imports *Remdesivir* from other countries. MoHFW has written to MEA on 03.05.2021 for exploring all possible options of procuring *Remdesivir* through Indian Missions abroad. MEA is placing orders for procuring 3 lakh doses of *Remdesivir* with a company called Eva Pharma in Egypt for supplies during May and 1st Week of June, 2021.

41. In addition, the MoHFW has secured donations of *Remdesivir* from other countries: 1.25 lakh vials through USAID, 4.50 lakh vials from M/s Gilead Sciences, USA and small quantities from other countries as well. Around 2.80 lakh doses have arrived and have been dispatched to consignee locations across the country. DCGI will continue to expeditiously process any applications for new drug permissions for *Remdesivir*.

42. As per Section 92 of the Patent Act, if the Central Government is satisfied, in respect of any patent in force in circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use, that it is necessary that compulsory licenses should be granted at any time after the sealing thereof to work the invention, it may make a declaration to that effect, by notification in the Official Gazette, and the Controller General of Patents, Designs & Trademarks shall on application made at any time after the notification by any person interested, grant to the applicant a Compulsory licence under the Patents Act.

43. As per Section 100 of the Patents Act, at any time after an application for a patent has been filed at the patent office or a patent has been granted, the Central Government and any person authorised in writing by it, may use the invention for the purposes of Government in accordance with the provisions of the Act.

44. In the current scenario, the main constraint is in availability of raw materials and essential inputs. Therefore, any additional permissions and licenses may not result in increased production immediately. It is difficult to predict the trend of the pandemic and therefore difficult to forecast the demand for *Remdesivir* with a reasonable degree of certainty. However, such permissions will build capacities to effectively handle any future crises.

45. It is presumptuous to assume that the patent holder will not agree to more voluntary licenses for such manufacturers who have a new drug manufacturing permission from the DCGI. However, if such a manufacturer applies for a compulsory license under section 92, the same may be suitably considered by the DoC.

46. Meanwhile the MoHFW, with the support of the DoP and the MEA, is making all efforts to enhance availability of *Remdesivir* through ramping up of production and sourcing through imports. However, in view of the current constraints on

availability of raw materials and other essential inputs, mere addition of more production capacity may not lead to the desired outcomes of enhanced supplies. It is difficult to predict the trend of the pandemic and therefore difficult to forecast the demand for *Remdesivir* with a reasonable degree of certainty. Therefore, it is communicated that, the matter of sending the proposal for invocation of the provisions of Section 100 of the Patents Act, 1970, is being processed.

47. It is respectfully submitted that this Hon'ble Court is examining these issues in very peculiar and unprecedented circumstances namely; the problem being handled by the central government is not India specific problem but a global problem. All countries of the world are affected by the virus which is clear from the fact that WHO has declared this to be “pandemic” and not “epidemic”. When there is a surge in cases and in demand of patented medicines/drugs/vaccines from all over the world the solution needs to be found out essentially at an executive level engaging at diplomatic levels. Any exercise of statutory powers either under the patents act 1970 read with Trips agreement

and Doha declaration or in any other way can only prove to be counter-productive at this stage, the central government is very actively engaging itself with global organisations at a diplomatic level to find out a solution in the best possible interest of India. It is earnestly urged that any discussion or a mention of exercise of statutory powers either for essential drugs or vaccines having patent issues would have serious, severe and unintended adverse consequences in the countries efforts being made on global platform using all its resources, good-will and good-offices though diplomatic and other channels.

48. So far as the drug Tocilizumab is concerned, it may be mentioned the applications for new drug permission for those who are applying for manufacturing permission, are being processed by CDSCO expeditiously

Re:- Allocation of Remdesivir injection to respective State/UT:-

49. At the outset, it is submitted that *Remdesivir* is a patented drug for which the patent holder Gilead USA granted voluntary

license to seven Indian manufacturers in 2020. Looking to the sudden and steep demand for *Remdesivir* injections in 2021, the government coordinated with the seven licensed manufacture of the drug to augment production immediately. With the expeditious approval granted by the DCGI (Drug Controller General of India), as mentioned above, to the licensed manufacturers who are licensed by the “Patent Holder” for the additional sites (ie additional manufacturing units), the productions capacity has gone up from 38 lk vials/month to the level of 1 Cr vials/month. In the normal course the State Governments and UTs were directly placing their purchase orders with the manufacturers for supply of *Remdesivir*. In addition, the manufacturers also supply their stocks through the private distribution channel. In the current situation where the significant gap in the demand and supply was observed, despite the increase in capacity, the Central Government has adopted a broad and dynamic framework of allocation of the supplies being made by the manufacturers to the states, in order to ensure equitable distribution of *Remdesivir* across the country to each

State. It has also been clarified to the states that this allocation covers the requirement of *Remdesivir* by both government and private hospitals situated within the respective State/UT. It is stated that the internal distribution of *Remdesivir* within the state is essentially and necessarily for each state government to monitor, so as to ensure that the internal distribution is equitable and no hoarding, black-marketing or any other malpractices takes place either in supply, sale or distribution of *Remdesivir* injection. Since, *Remdesivir* is expected to be used as investigational therapy for patients with moderate to severe stage of COVID infection to a patient on oxygen according to the National Treatment Protocol for COVID 19, the initial allocation was made commensurate with the oxygen allocation made by central government to some States at that point. However, the process of allocation being dynamic in nature, the central government immediately started taking into account the number of active cases in the respective states and UTs also as a parameter. This is also in tune with the requests made by several states to take into account their active case load while

allocating the requisite quantities of *Remdesivir* injection to the said State.

50. It is submitted that the actual rate of production of *Remdesivir* is given above. It may be noted that demands placed by the states vary on account of variations in their respective procurement policies and systems prevailing earlier. Prior to or at the very initial beginning of the second wave, some states may have already purchased a substantial stock of *Remdesivir* according to their procurement policies , and therefore, their demand could be comparatively less. Moreover, at the time of the very initial surge itself, it was found that the states in which the manufacturing units of *Remdesivir* are situated are persuading the manufacturers to stockpile *Remdesivir*, and therefore, it was found imperative that allocation be made at a central level so that the states which incidentally do not have manufacturing units within it are not put to unfair disadvantage.

51. At present the allocation of *Remdesivir* is being made after considering the feedback from the State(s). Thus, the allocation of *Remdesivir* is being made equitably, though in a dynamic manner, based upon and commensurate with the allocation of oxygen, number of active cases in the State and keeping in mind the evolving availability of supplies. It may be pertinent to note that. as the production of *Remdesivir* has been increased, till date, allocation has been revised to 53 lakh vials for the period 21.04.2021 – 16.05.2021 through a series of allocation orders issued to State Governments

52. It is submitted that the augmentation of manufacture of *Remdesivir* involves certain constraints including limited availability of certain inputs. In fact, all steps are being taken to augment the supply both within the country by increased production, and from outside the country by placing orders for import. Considering all the circumstances and constraints which are inevitable, the central government has provided for a rational, reasonable, non-arbitrary, transparent and equitable system of distribution. This methodology also factors in several

day-to-day exigencies which would not be possible to be anticipated in exercise of judicial review by this Hon'ble Court. This Hon'ble Court may therefore, not interfere with this *suo moto* jurisdiction or otherwise either on the basis of and/or even if some alternative system is suggested.

Re:- Issue regarding pricing of drugs as mentioned in Para 51 of this Hon'ble courts judgment dated 30.04.2021:

53. So far as the contents of para 51 of the order and judgment dated 30.04.2021 are concerned this Hon'ble Court was pleased to require the central government to consider invoking certain statutory powers of Drugs (Prices Control) Order, 2013. It is submitted that the same is under consideration of the Central Government.

54. Considering the global scenario, sudden surge of demand for the drugs globally, the availability of raw material for manufacturing important drugs from other countries and the difficulty faced on that account and other factors, it is decided, after a careful consideration that subject to exercise of statutory

powers at an opportune time in future, at present the priority areas shall be directed to augment production, ensure effective and equitable distribution and ensure availability of essential drugs under any circumstances.

55. The central government has, however, after repeated consultations and other methods ensured that *Remdesivir* manufacturers reduce their prices. Such efforts have yielded results and the prices of *Remdesivir* have gone down by 25% to 50%. Thus, exercise of statutory power shall have to be a calibrated executive response keeping several factor national and global factors in mind and the central government does not intend to close the said option.

56. It is however submitted that considering the totality of facts and all relevant factors into consideration the central government has already exercised its powers under the relevant provisions of Drug Price Control (Order) 2013 to fix the ceiling prices in case of *Enoxaparin, Methylprednisolone, Paracetamol and Hydroxy-chloroquine*. Further the central government is

monitoring the retail prices of non-scheduled medicines namely, *Favipiravir, Remdesivir, and Ivermectin*, under para 20 of Drug Price Control (Order) 2013, wherein, no annual increase in MRP beyond 10 % is permitted. These powers are being exercised in addition to the voluntary reduction in prices of *Remdesivir* as stated above, which the manufacturers have agreed to.

Re:- Issue Of Imports as mentioned in para 52 of the judgment of this Hon'ble Court:-

57. It is submitted that making all drugs available for covid 19 is on the top-most priority of the central government. By using all its power, international goodwill and diplomatic routes the central government is making all efforts to import essential drugs fighting against the constraints like the very same drugs being required globally by every country. The central government has procured some doses of *Remdesivir* and has placed further orders for the same. These efforts are going on a war footing.

Re:- issue of Demand, production and supply of drugs/medicines used to treat COVID 19 patient as mentioned in para 53 and 54 of this Honble Courts Judgment dated 30.04.2021:-

58. The estimation of demand and assessment of the existing stocks and production capacity of manufacturers is an ongoing exercise. The assessment of availability and augmentation of production is being taken up both for the drugs included in the National Treatment protocol and other drugs found to be in demand. Hence the list of drugs to be monitored for availability is continuously updated.

59. As regards *Remdesivir* and Tocilizumab, the Ministry of Health and Family Welfare and Department of Pharmaceuticals have jointly undertaken the exercise of allocation of available supplies across the states / UTs in order to facilitate availability of the two drugs across the country in view of the surge in demand. A total of 34.50 lakh vials have been allocated for the period 21.04.21 to 09.05.2021 through a series of allocation orders, against which 33.96 lakh vials have been supplied till 7th May 2021. The allocation and supply position of *Remdesivir*

is Annexed hereto and marked as Annexure R/7. The last order dated 07.05.2021 revised the allocation for the period 21.04.2021 to 16.05.2021 to 53 lakh vials.

60. In the case of Tocilizumab, as the country is entirely dependent on imports, out of the limited stock of vials imported in the country on 26.04.2021, 3245 vials were allocated to states on 27.04.2021 and additional allocation of 6655 vials was done on 30.04.2021 to states and central allocation of 1200 vials has been kept with MoHFW for central institutes, UTs and NER. The allocation and supply position of Tocilizumab is annexed hereto and marked as Annexure R/8. It is stated that about 6478 vials have been supplied till 7th May 2021. The efforts are underway to procure, import more Tocilizumab.

61. Major manufacturers of the other drugs being used in COVID 19 treatment are already identified from DCGI and Sales database and the regular interaction with the manufacturers are going on. It has been already submitted to this Hon'ble Court that a meeting was held on 25th April 2021

by DoP, NPPA and DCGI with the manufacturers to review stock position, availability and production plans. It is to further submit that a subsequent meeting was held on 3rd May, 2021 with Empowered Group-1 (chaired by Dr V.K Paul, Member Health NITI Aayog) formed by the Central Govt on “Medical Infrastructure and COVID Management Plan”, attended by MoHFW, DCGI, Medical Experts and two representatives of State Governments. The meeting discussed the drugs which should be focussed upon and firming up of its projected demand in the country in the ongoing pandemic and demand projections. The efforts with drug manufacturers to augment the production of other drugs, is being further aligned with the demand projections and a series of four meetings have been held with manufacturers between 5th May and 8th May 2021.

62. Average monthly production as given by major manufacturers and projected requirement for the month of May as estimated by Joint Monitoring Group of Director General

Health Services (DGHS) for the relevant drugs is given in table below:

S. No	Name of the Drug	Average Monthly Production (Qty in lakh)	Projected requirement in lakh by Joint Monitoring group under DGHS for 30 days*	Availability of API to meet Projected Demand
1	Dexamethasone Injection	119	170	Yes
2	Methyl-prednisolone Injection	6.5		Yes
3	Favipiravir Tablet	1121	**-	Production being enhanced and orders placed for input supplies
4	Enoxaparin Injection	40	271	
5	Ivermectin Tablets	180	90 289	
6	Hydroxy Chloroquine	550		Yes
7	Paracetamol	4000	903	Yes

* the projected requirement is as per recommended guidelines and indicates the likely maximum and includes buffer, but actual requirement would be based on treatment decisions, the current trend and extent of the pandemic in the country.

** Not recommended by JMG being not a part of National Treatment Protocol

For convenience of this Hon'ble Court a copy of the results of the survey on availability of essential medicines like Methyl

Prednisolone, Dexamethasone etc in chemist shops is annexed hereto and marked as Annexure R/9.

63. The manufacturers of the drugs listed have been advised to augment production to meet the projected requirement and ensure the availability of the API and inputs. The Government is closely watching the supply situation of the other drugs and the intervention of Govt of India for making allocation of these drugs, on the lines done for *Remdesivir* and Tocilizumab, a decision will be taken if required.

Re:- Issue medicine/drugs being sold on inflated prices or in fake form in the domestic market as mentioned in para 56 of this Honble Courts Judgment dated 30.04.2021:-

64. It is submitted that Sale and distribution of drugs are regulated under the Drugs and Cosmetics Act, 1940 and the Drugs Rules,1945 by the State Licensing Authorities (SLAs) appointed by the State Governments. License to sale and distribution of drugs are granted by the SLAs.

65. DCGI has taken a number of measures to check any hoarding and black marketing of drugs. DCGI had instructed all State Drugs Controllers (SDCs) on 10.04.2021 to conduct special investigation drive to prevent hoarding/black marketing on *Remdesivir* in the country and action taken is being followed up by the CDSCO regularly. On 24.04.21, DCGI had communicated to all the SDCs that there should be zero tolerance to any kind of hoarding/ black marketing of drugs and again asked to instruct their enforcement staff to keep strict vigil at the sensitive places and to take stringent action against black marketing / hoarding of drugs. Further, on 27.04.21, DCGI has again reminded all the SDCs for taking stringent action in the matter. Further, the Central Drugs Standards Control Organisation (“CDSCO”) has also collected information from the SDCs regarding details of the Enforcement actions taken in this regard. The enforcement actions have been taken in 157 cases in various places across the country, which include actions like filing cases/ lodging FIRs, arresting people involved in such activities, etc. Copies of the letter dated 10.04.2021, 24.04.2021,

27.04.2021 written by Drugs Controller General of India and the letter dated 7.05.2021 by the MoHFW to prevent hoarding and black marketing of the essential drugs is annexed hereto and marked as Annexure R/10.

66. The Ministry of Health & Family Welfare, vide letter no. X.11035/130/2021-DRS, dated 07.05.2021, has also requested the State Governments for taking all necessary measures to stop black marketing/ hoarding etc. under the provisions of the Drugs and Cosmetics Act, The Essential Commodities Act and other applicable Rules and Regulations

67. The question of black-marketing is essentially dealt with sternly by use of police administration and local state administration. Law and order being a state subject all state governments must ensure special teams at state district and taluka levels to mercilessly clamp down on any illegal hoarding or black marketing and send a clear message that trading in human miseries shall not be tolerated under any circumstances.

HEALTHCARE WORKERS – STEPS TAKEN THEREOF

68. The updated information pertaining to claims under the Insurance scheme for Healthcare Workers, under the Pradhan Mantri Garib Kalyan Package, are as under –

- The scheme is being implemented through purchase of an insurance policy from the Public Sector New India Assurance Company Ltd.
- With effect from April 24, 2021, the insurance policy with M/S New India Assurance Company has been renewed for a period of 180 days. It can be further extended, if need be.
- At present, 331 claims have been processed. Out of these, 310 have been paid and for the remaining 21, nominee details are awaited.
- 525 claims are presently under examination. Sincere endeavour is being made to settle all the pending claims received till April 2021 within next three months which is the outer limits. The Insurance Company is now proactively engaging with the survivors of the deceased

healthcare workers to help in documentation to avoid any delay on this account. The central government is making all out efforts in collaboration with the respective State/UT Governments for early submission, processing and settlement of the claims.

69. It is submitted that further, the health care workers were facilitated to work in COVID environment through the following activities:

- i. Health care workers are trained on multiple platforms for differential skill sets appropriate to their level for managing Covid 19. Key areas for training involved surveillance, contact tracing , supervision of home isolation, laboratory support, clinical management and risk communication.
- ii. Plans/ procedures/protocols were made available to facilitate the work of Health care workers such as .
 - (a) guideline on Infection Prevention and Control practices.

- (b) rational use of PPEs for hospital and community settings guidelines followed a risk-based approach and recommended type of PPE that needs to be used in high and low risk areas
 - (c) Guidelines on managing mental health at times of COVID
 - (d) Advisory for managing HCWs working in Covid and non-covid areas of the hospital
- iii. The healthcare workers were provided with hydroxychloroquine for prophylaxis and prevention of infection. MoHFW also issued an advisory to that affect on 23rd March 2020.
- iv. Prescribed and provided protective equipment appropriate to their work settings to protect Health Care workers from Covid 19. This included supply of personal protective equipment, mask (medical and N 95), gloves etc. So far 1.77 crore of PPE Kits, 4.22 crores N-95 masks, 11.16 crore tablets of Hydroxychloroquine have been supplied to

States/UTs/ Central Government institutions. (as reported on 9th May 2021).

- v. In case of high risk exposure, healthcare workers are provided a quarantine period initially for one week and thereafter taking the profile of the health worker a decision to be taken for further period of one week.
- vi. Ministry of Health & Family Welfare in consultation with Department of Personnel Training has also directed State Governments to consider quarantine period of healthcare workers as 'on duty'. The State Governments shall have to place these facts as implemented by them.
- vii. Union Ministry of Health & Family Welfare has also issued direction to the Chief Secretary of the States/Union Territories on provision for accommodation facilities for quarantine of healthcare workers. States/UTs were also advised to explore various rostering options. The State Governments shall have to place these facts as implemented by them.

- viii. MoHFW on 18th June 2020, as per directions issued by Hon'ble Supreme Court in a batch of writ petitions and in exercise of powers delegated under section 10(2) of the Disaster Management Act, 2005 has issued directions that States/UTs to ensure that salaries of doctors and healthcare workers during COVID-19 related duties shall be released on time.
- ix. In the context of COVID-19, the Epidemic Diseases (Amendment) Ordinance, 2020 was promulgated on 22nd April 2020. Further this ordinance, brought before the Parliament has been passed and notified on 29th September 2020. The amendment provides for safety and security of Health care Service Personnel (HSPs) from acts of violence. It provides for making any act of violence against Health Care personnel or causes damage to any property a cognizable and non-bailable offence punishable with imprisonment for a term which shall not be less than three months but extendable up to five years.

- x. Provided an incentive of Rs one thousand per month to all ASHAs for managing Covid 19 apart from the usual incentives paid to ASHAs for their other non-COVID health related work. The financial requirement was met from National Health Mission (NHM).
- xi. Life Insurance benefits (Rs. 50 lakhs to 22.12 lakh healthcare providers) are being provided under Pradhan Mantri Garib Kalyan Package (PMGKP): Insurance Scheme for Health Workers Fighting COVID-19. The benefits under the said scheme have been extended for a further period of 180 days (w.e.f. 24.04.2021).
- xii. To begin-with, Health Care workers were prioritized for vaccination as a priority group when the nation wide vaccination was launched since 16th January 2021. Till date, 1.60 crore doses have been administered to Health Care Workers (95.39 lakh 1st doses and 64.61 lakh 2nd dose).

xiii. Inspirational series on Health Care Workers were uploaded on public domain touching upon various facets such as facilitation for the work, de-stigmatization of their services, etc.

70. Lastly, it is submitted that as far as observations at para 59 of the judgment/order dated 30.04.2021 are concerned, the Central Government is already utilising the health care workforce available with the armed forces and para military forces during the pandemic. Further, plan for utilisation of the same for the purpose of vaccination are under active consideration and is being considered on need basis.

71. The present affidavit is bonafide and in the interest of justice.



DEPONENT

(गोविन्द मोहन)
 (GOVIND MOHAN)
 अपर सचिव (यूटी)
 Additional Secretary (UT)
 मुख्य मंत्रालय
 Ministry of Home Affairs
 नई दिल्ली - 110001
 North Block, New Delhi-110001

VERIFICATION

I, the deponent abovenamed, do hereby verify that the contents of Para 1 to 86 of my above affidavit are prepared on the basis of instructions received by me from respective ministries i.e. Ministry of Health and Family Welfare, Department of Pharmaceuticals, Ministry of Home Affairs, Ministry of Chemicals and Fertilizers, Department of Industrial Policy and Promotion, Department for Promotion of Industry and Internal Trade, Ministry of Commerce and Industry etc. who as per the allocation of business rules are obligated to respond to the orders passed by this Hon'ble Court and on the basis of legal advice received and no part of it is false and nothing material has been concealed there from to the best of my knowledge.

Verified at New Delhi on this the 09.05.2021.



DEPONENT

(गोविन्द मोहन)
 (GOVIND MOHAN)
 अपर सचिव (यूटी)
 Additional Secretary (UT)
 मुख्य मंत्रालय
 Ministry of Home Affairs
 नई दिल्ली-110001
 North Block, New Delhi-110001

DEPONENT

IN THE SUPREME COURT OF INDIA
CIVIL ORIGINAL JURISDICTION

Suo Motu Writ Petition (Civil) No.3 of 2021

**IN RE: DISTRIBUTION OF ESSENTIAL SUPPLIES AND SERVICES
DURING PANDEMIC.**

O R D E R

This order has been divided into the following sections to facilitate analysis:

- A Introduction**
- B Outline of the Disaster Management Act**
- C Medical Infrastructure**
 - C.1 Submissions in UOI's Affidavits**
 - C.2 National Policy for Admission in Hospitals**
- D Oxygen allocation and availability**
- E Vaccines**
 - E.1 Vaccine capacity and disbursal**
 - E.2 Vaccine pricing**
- F Potentiality of Compulsory Licensing for vaccines and essential drugs**
- G Supply of Essential Drugs**
 - G.1 Submissions in the Central Government's Affidavits**
 - G.2 Recommendations**
 - G.3 Black Marketing**
- H Recommendations for augmenting healthcare workforce**
- I Epilogue**
- J Conclusion**

A Introduction

1 The genesis of this *suo motu* writ petition is in an order dated 22 April 2021. This Court took note of the unprecedented humanitarian crisis in the country, following the outbreak of the COVID-19 pandemic. Notices were issued to the Union of India¹, the Governments of the States and Union Territories², and to several petitioners who were before the High Courts. The Court observed:

“the Union Government, the State Governments/Union Territories and the parties, who appeared to have approached the High Courts to show cause why uniform orders be not passed by this Court in relation to
 a) Supply of oxygen;
 b) Supply of essential drugs;
 c) Method and manner of vaccination; and
 d) Declaration of lockdown”

The Court directed the Central Government to :

“1. Report on the existence or otherwise and requirement of setting up of a coordinating body that would consider allocation of the above resources in a consultative manner (with the involvement of concerned States and Union Territories).
 2. Consider declaration of essential medicines and medical equipment including the above articles as essential commodities in relation to COVID.
 3. In respect of coordination of logistical support for inter-State and intra-State transportation and distribution of the above resources.”

2 The Court also had appointed an *Amicus Curiae* to assist it. However, the *Amicus Curiae* was, on his request, relieved of his position on 23 April 2021. Hearings in the matter were then conducted on 27 April 2021, where the Court appointed two new *Amici*: Mr Jaideep Gupta and Ms Meenakshi Arora, learned Senior Counsel. They will be assisted by Mr Kunal Chatterjee and Mr Mohit Ram,

¹ “UOI”, referred interchangeably as “Central Government”

² Collectively referred as “State Government”

learned counsel and Advocate-on-Record. The Court began the hearing by noting that the jurisdiction it assumed under Article 32 did not automatically lead to the erosion of a High Court's jurisdiction under Article 226. Rather, the Court stressed on the importance of the jurisdiction under Article 226, and how High Courts may be better equipped to deal with issues within their own States. However, this Court assumed jurisdiction over issues in relation to COVID-19 which traverse beyond state boundaries and affect the nation in its entirety.

3 The Court noted that it was in receipt of an affidavit dated 23 April 2021 filed by the UOI. However, the Court directed the UOI to file an additional affidavit and the respective governments of the States/Union Territories to file fresh affidavits on four issues. The relevant extract of the order reads thus:

- “(i) Supply of oxygen – The Court should be apprised by the Union of India on
- (a) The projected demand for oxygen in the country at the present point of time and in the foreseeable future;
 - (b) The steps taken and proposed to augment the availability of oxygen, meeting both the current and projected requirements;
 - (c) The monitoring mechanism for ensuring the supply of oxygen, particularly to critically affected States and Union Territories as well as the other areas;
 - (d) The basis on which allocation of oxygen is being made from the central pool; and
 - (e) The methodology adopted for ensuring that the requirements of the States are communicated to the Central Government on a daily basis so as to ensure that the availability of oxygen is commensurate with the need of each State or, as the case may be, Union Territory.
- (ii) Enhancement of critical medical infrastructure, including the availability of beds, Covid treatment centres with duly equipped medical personnel on the basis of the projected requirement of healthcare professionals and anticipated requirements. The Union government will consider framing a policy specifying the standards and norms to be observed for admitting patients to hospitals and covid centres and the modalities for admission;

(iii) The steps taken to ensure due availability of essential drugs, including Remdesivir and Favipiravir among other prescribed drugs and the modalities which have been set up for controlling prices of essential drugs, for preventing hoarding and for ensuring proper communication of the requirements at the level of each District by the District health authorities or Collectors to the Health Departments of the States and thereafter by the states to the Union Ministry of Health and Family Welfare so that the projected requirements are duly met and effectively monitored on a daily basis.

(iv) Vaccination

(a) Presently two vaccinations have been made available in the country, namely, Covishield and Covaxin;

(b) As of date, the vaccination programme has extended to all citizens of the age of 45 years and above;

(c) From 1 May 2021, the vaccination programme is to be opened up also to persons between the age groups of 18 to 45, in addition to the existing age group categories. The Union of India shall clarify (i) the projected requirement of vaccines as a result of the enhancement of coverage; (ii) the modalities proposed for ensuring that the deficit in the availability of vaccines is met; (iii) steps proposed for enhancement of vaccine availability by sourcing stocks from within and outside the country; (iv) modalities for administering the vaccines to meet the requirements of those in the older age group (forty five and above) who have already received the first dose; (v) modalities fixed for administering the vaccine to meet the additional demand of the 18-45 population; (vi) how the supplies of vaccines will be allocated between various states if each state is to negotiate with vaccine producers; and (vii) steps taken and proposed for ensuring the procurement of other vaccines apart from Covishield and Covaxin and the time frame for implementation; and

(d) The basis and rationale which has been adopted by the Union government in regard to the pricing of vaccines. The government shall explain the rationale for differential pricing in regard to vaccines sourced by the Union government on one hand and the states on the other hand when both sources lead to the distribution of vaccines to citizens."

4 This Court then received an additional affidavit dated 29 April 2021 from the UOI, and fresh affidavits by the various States/UTs addressing the four issues mentioned in its order dated 27 April 2021. In the hearing conducted on 30 April 2021, this Court heard submissions by Mr Tushar Mehta, learned Solicitor

General of India, who was appearing on behalf of the Central Government. Several other counsels have made brief interjections, including Mr Vikas Singh, Senior Counsel and President of the Supreme Court Bar Association. This Court also heard a presentation on oxygen supply in India by Ms Sumita Dawra, Additional Secretary, Department of Promotion of Industry and International Trade, Ministry of Commerce and Industry. As such, unless specified otherwise, the directions and observations in the present order are limited to the UOI.

5 During the course of the hearing, this Court directed that the individual States/UTs shall be given an opportunity to discuss their affidavits at a later hearing. Further, the Court also directed the learned *Amici* to prepare a tabular compilation in relation to all the Interlocutory Applications which have been filed in this petition. On the basis of the issues raised, they shall also be considered in a later hearing. Before delving into a substantive discussion, we would like to clarify that the jurisdiction exercised in this matter is merely to facilitate a dialogue of relevant stakeholders, the UOI, the States and this Court, in light of the pressing humanitarian crisis, and not with a view to usurp the role of the executive and the legislature. This bounded-deliberative approach³ is exercised so that the UOI and States can justify the rationale behind their policy approach which must be bound by the human rights framework which presently implicates the right to life under Article 21 and right to equality under Article 14 of the Constitution.

³ Sandra Fredman, "Adjudication as Accountability: A Deliberative Approach" in Nicholas Bamforth and Peter Leyland (eds), *Accountability in the Contemporary Constitution* (Oxford University Press, 2013)

B Outline of the Disaster Management Act

6 The Disaster Management Act, 2005⁴ came into effect on 26 December 2005. The DMA provides for the effective management of disasters and matters connected or incidental to such disasters. COVID-19 falls under the definition of a disaster under Section 2(d)⁵ of the DMA and the provisions of the DMA were invoked for the first time to deal with the present pandemic. Under Section 6(2)(i) of the DMA, the National Disaster Management Authority⁶ issued an order dated 24 March 2020 directing the Ministries, UOI, State/UTs and their authorities to take effective measures to prevent the spread of COVID-19 in the country. Thereafter, the Home Secretary, Ministry of Home Affairs as the Chairperson of the National Executive Committee, which assists the NDMA in its functions, in an order dated 24 March 2020 issued guidelines for the initial 21 days' lockdown on account of COVID-19.

7 Section 2(e) defines disaster management as a continuous and integrated process of planning, organizing, coordinating and implementing measures in relation to the disaster. Section 2(e) provides:

"2...

(e)"disaster management" means a continuous and integrated process of planning, organizing, coordinating and implementing measures' which are necessary or expedient for--

- (i) prevention of danger or threat of any disaster;
- (ii) mitigation or reduction of risk of any disaster or its' severity or consequences;
- (iii) capacity-building;

⁴ "DMA"

⁵ "...(d) "disaster" means a catastrophe, mishap, calamity or grave occurrence in any area, arising from natural or man-made causes, or by accident or negligence which results in substantial loss of life or human suffering or damage to, and destruction of, property, or damage to, or degradation of, environment, and is of such a nature or magnitude as to be beyond the coping capacity of the community of the affected area;"

⁶ "NDMA"

- (iv) preparedness to deal with any disaster;
- (v) prompt response to any threatening disaster situation or disaster;
- (vi) assessing the severity or magnitude of effects of any disaster;
- (vii) evacuation, rescue and relief;
- (viii) rehabilitation and reconstruction;..”

Section 2(n) of DMA defines a “National Plan” as the plan for disaster management for the whole country prepared under Section 11 of DMA. Section 3 of the DMA constitutes the NDMA with the Prime Minister as the Chairperson, *ex officio*. Section 6 lists down the powers and functions of the NDMA. Under Section 6(2)(b), NDMA has the power to approve the National Plan. Section 11 of the DMA provides the procedure for drawing up and implementation of the National Plan in the following terms:

“11. National Plan

- (1) There shall be drawn up a plan for disaster management for the whole of the country to be called the National Plan.
- (2) The National Plan shall be prepared by the National Executive Committee having regard to the National Policy and in consultation with the State Governments and expert bodies or organisations in the field of disaster management to be approved by the National Authority.
- (3) The National Plan shall include--
 - (a) measures to be taken for the prevention of disasters, or the mitigation of their effects;
 - (b) measures to be taken for the integration of mitigation measures in the development plans;
 - (c) measures to be taken for preparedness and capacity building to effectively respond to any threatening disaster situations or disaster;
 - (d) roles and responsibilities of different Ministries or Departments of the Government of India in respect of measures specified in clauses (a), (b) and (c).
- (4) The National Plan shall be reviewed and updated annually.
- (5) Appropriate provisions shall be made by the Central Government for financing the measures to be carried out under the National Plan.
- (6) Copies of the National Plan referred to in sub-sections (2) and (4) shall be made available to the Ministries or Departments of the Government of India and such Ministries

or Departments shall draw up their own plans in accordance with the National Plan."

8 A National Plan includes, *inter alia*, measures for disaster prevention, mitigation, preparedness and roles and responsibilities of different Ministries in terms of Section 11(3) of DMA. A National Plan for the entire country was prepared in the year 2016 and was revised and notified in November, 2019. The National Plan, 2019 provides a framework to the Government agencies to deal with different aspects of disaster management. Section 11(4) of the DMA provides that the National Plan is to be revised and updated annually making it a 'dynamic document'. The executive summary of the National Plan succinctly captures its purpose and contours in the below extract:

"...The National Disaster Management Plan (NDMP) provides a framework and direction to the government agencies for all phases of disaster management cycle. The NDMP is a "dynamic document" in the sense that it will be periodically improved keeping up with the emerging global best practices and knowledge base in disaster management. It is in accordance with the provisions of the DM Act, 2005, the guidance given in the National Policy on Disaster Management (NPDM) 2009, and the established national practices..."

9 Section 12 of the DMA empowers the NDMA to recommend guidelines for the minimum standard of relief to be provided to persons affected by disaster. NDMA can create guidelines stipulating minimum standards of relief for providing ex gratia assistance on account of loss of life and restoration of means of livelihood in terms of Section 12(iii) of DMA. In light of the human suffering and loss of livelihood that has accompanied this pandemic, NDMA may consider laying down minimum standards of relief in this regard. We clarify that this is not

a direction of this Court, however a suggestion that can be looked into by the NDMA. Under Section 12(iv) of the DMA, the NDMA has been given wide powers to provide guidelines for any such relief that may be necessary.

10 In addition to the above provisions, Section 35 of the DMA empowers the Central Government to take measures which it deems to be necessary or expedient for the purpose of disaster management. Section 35(2)(a) provides for coordination of actions between the Central Government and State Governments and their respective authorities in relation to disaster management. Section 35(2)(e) obliges the Central Government to assist and cooperate with the State Governments as requested by them or otherwise deemed appropriate by it.

11 Section 36 of DMA provides for the responsibilities that have to be undertaken by the Ministries or Departments of the Central Government. While Section 36(h) empowers the Central Government to take any actions that it may consider necessary for disaster management, Section 36(d) specifically enables it to review its policies with a view to incorporate provisions necessary for prevention of disaster, mitigation or preparedness. Under Section 36(f), it is the responsibility of every Ministry or Department of Central Government to provide assistance to the State Governments for (i) drawing up mitigation, preparedness and response plans, capacity-building, data collection and identification and training of personnel in relation to disaster management; (ii) carrying out rescue and relief operations in the affected area; (iii) assessing the damage from any disaster; and (iv) carrying out rehabilitation and reconstruction. Section 35(g) provides that the Central Government is responsible for making available its resources to the National Executive Committee or a State Executive Committee

for the purposes of, *inter alia*, transporting personnel and relief goods to and from the affected area.

12 The provisions of Sections 35 and 36 of the DMA that have been discussed above have been enacted in the spirit of cooperative federalism in order to ensure that Central Government can assist and enable the State Governments to effectively tackle the disaster in question.

13 The learned Solicitor General has submitted that the Central Government is operating under the broad framework of the National Plan and the plan is already in force. The plan specifically deals with “Biological and Public Health Emergencies”. Further, different States have their own Disaster Management Plans in place. It has been submitted that the National Plan does not and cannot contain step by step instructions or specific directions for the day to day management of the pandemic by the Government agencies. Such aspects are kept open for executive decision, in view of the dynamic nature of the disaster in question. Further, since COVID-19 is a novel virus, the knowledge in relation to such a virus is contemporaneous in nature and is subject to constant development. A three Judge bench of this Court in its judgement in **Centre for Public Interest Litigation vs Union of India⁷** had noted that there was no need to develop a fresh National Plan under Section 11 for COVID-19 since a National Plan was already in place, which was being supplemented by various orders and measures taken by competent authorities under DMA. Justice Ashok Bhushan, speaking for this Court, observed that:

⁷ 2020 SCC OnLine SC 652

"40. The Disaster Management Act, 2005 contain ample powers and measures, which could be taken by the National Disaster Management Authority, National Executive Committee and Central Government to prepare further plans, guidelines and Standard Operating Procedure (SOPs), which in respect to COVID-19 had been done from time to time. Containment Plan for Novel Coronavirus, 2019 had been issued by Ministry of Health and Family Welfare, Government of India. There were no lack of guidelines, SOPs and Plan to contain COVID-19, by Nodal Ministry had been brought on record issued by Ministry of Health and Family Welfare, Government of India, i.e., Updated Containment Plan for Large Outbreaks Novel Coronavirus Disease, 2019 (COVID-19)."

14 Therefore, the National Plan, 2019 can be supplemented by the issuance of additional guidelines to tackle any aspect of disaster management including the issue of admission to hospitals and access to essential drugs and vaccines in respect of COVID-19.

C Medical Infrastructure

C.1 Submissions in UOI's Affidavits

15 In relation to the broad issue of medical infrastructure, the Central Government begins its affidavit dated 23 April 2021 and additional affidavit dated 29 April 2021 by describing its 'three-tier setup' of Covid Care Centers⁸, Dedicated COVID Health Centers⁹ and Dedicated COVID Hospitals¹⁰ which was recommended to the States for tackling the COVID-19 pandemic, for which the UOI also provided funds under an emergency response package from the National Health Mission and State Disaster Response Fund.

⁸ "CCC"

⁹ "DCHC"

¹⁰ "DCH"

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16 The present status of these is: (i) 2,084 DCH (of which 89 are under the Central Government and the rest 1,995 with State Governments); (ii) 4,043 DCHC; and (iii) 12,673 CCC. Cumulatively, they have 18,52,265 beds in total, out of which 4,68,974 beds are in DCH. It was also noted that Central Government hospitals have also been converted into DCH.

17 Further, tertiary care hospitals under ESIC, Defence, Railways, paramilitary forces, Steel Ministry, *et al*, are also being leveraged for case management. Even as many as 3816 railways coaches spread over 16 railway zones have been converted into CCC. Finally, the DRDO has also set up large field hospitals with capacities ranging from 1,000 to 10,000 isolation beds.

18 It was noted that through coordination between Central Government and State Governments, isolation beds (with/without oxygen) were increased to around 15.7 lakhs, as compared to 10,180 before the first lockdown; similarly, ICU beds were increased to more than 85,000, as compared to 2,168 before the first lockdown. Similar upgrades were provided to necessary equipment such as Ventilators, N95 masks and PPEs.

19 The affidavit provides the following details of the efforts taken by UOI to create projections for each State, and how it was communicated to them:

- (i) It has developed an IT module for projections of expected cases based on ongoing caseload, so as to alert States and districts to be prepared in advance. The projections by the Central Government were regularly shared in writing with the States, along with reports containing emergency

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plans. This tool was also made available to States, to map their own projections at the State level;

- (ii) Details of the meetings conducted by the Prime Minister, the Minister of Health and Family Welfare, the Cabinet Secretary, the Secretary (H) and the DGHS were provided; and
- (iii) Details of letters (which seem to have been sent on a monthly basis) sent by the Central Government to the State Governments indicate that they informed the State Governments of the projected cases for the coming month, along with the number of Oxygen Supported Beds, ICU Beds and of Ventilators that will be required to manage the projected cases. Thereby, the State Governments which were found lacking in their numbers were directed to ramp up their facilities.

20 In relation to the preparedness for the second wave of the COVID-19 pandemic, the affidavits state that:

- (i) After the first wave, the Central Government has been consistently writing to the State Governments from 4 December 2020 with numbers of projected cases, along with the directions requiring them to arrange the necessary infrastructure which will be needed;
- (ii) State Governments were requested by the UOI to formulate a comprehensive plan in relation to:
 - (a) Bed capacities, ICU beds, further identification of additional hospitals, preparation of field hospital facilities, ensuring sufficient oxygen supported beds and oxygen supplies;

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- (b) Deployment of requisite HR training and mentoring of doctors and nurses for management of patients, strengthen ambulance services and centralized call center-based services for allocation of beds;
- (c) Suitable initiatives for (among other things) achieving and maintaining adequate level of testing, surveillance and risk communication for promoting wearing of masks, physical distancing, hand hygiene;
- (d) Sufficient referral linkages for districts with deficit infrastructure through deployment of additional ambulances, wherever necessary; and
- (iii) On 20 April 2021, the Ministry of Health and Family Welfare¹¹ wrote to the State Governments with their projections and reminded them also of the funding avenues being made available to all States under NHM funding, State Disaster Response Fund, and other initiatives.

21 The affidavits also note that the Central Government had developed a live portal with all the States and districts where they were asked to feed in their data of cases and details such as people under home isolation, on isolation beds (with or without oxygen) and on ICU beds. Further, the State Governments were also directed to feed in details of the COVID dedicated health care infrastructure created by them, besides the details of containment zones so specified by them. However, the Central Government has alleged that States and districts did not upload their data regularly enough. Additionally, there was also a 'Facility App' which could be used by Covid Health facilities to monitor their patients as well as the availability of logistics with their health facility. However, the Central

¹¹ "MoHFW"

Government alleges that States, districts and facilities did not use this Facility App.

C.2 National Policy for Admission in Hospitals

22 It has been submitted by the Central Government that health being a state subject, the medical infrastructure is largely created and maintained by the respective State Governments. Since we are yet to hear from the State Governments, we shall not be issuing any directions or making comprehensive observations in relation to this issue.

23 However, based on the affidavits submitted by the Central Government and the hearings which followed, we have come to understand that there is no national policy on how admissions must take place in the various tiers of hospitals (CCC, DCHC and DCH). Gaining admission into a hospital with a bed is one of the biggest challenges being faced by most individuals during this second wave of the COVID-19 pandemic. Left to their own devices, citizens have had to suffer immeasurable hardship. Different states and local authorities follow their own protocols. Differing standards for admission in different hospitals across the nation leads to chaos and uncertainty. The situation cannot brook any delay. Accordingly, we direct the Central Government to frame a policy in this regard, in exercise of its statutory powers under the DMA, which will be followed nationally. The presence of such a policy shall ensure that no one in need is turned away from a hospital, due to no fault of their own. Such a policy should, *inter alia*, address the following issues in relation to admission:

- (i) Requirement of a positive test for COVID-19 virus, which may become difficult for many individuals since testing facilities are overwhelmed, test results are taking inordinately long time and the new strain of the COVID-19 virus is sometimes not even picked up by a regular RT-PCR test;
- (ii) Some patients are being refused service based on arbitrary factors. For example, the hospitals in Ahmedabad were initially refusing to take in patients who did not arrive in the government-run ‘108’ ambulances. While this rule has now been removed, after objections were noted by the Gujarat High Court during hearings in a *suo motu* public interest litigation¹², we note that such rules cannot be allowed to crop up in other places;
- (iii) Some reports have also been brought to our attention that hospitals are refusing to admit individuals who cannot produce a valid ID card which shows that they belong to the city where the hospital is located. Given how overstretched our hospitals are during the second wave of the COVID-19 pandemic, it is entirely plausible that individuals may travel to other cities in desperation, since beds may not be available in their city. The rural health infrastructure is seriously deficient. Hence, no hospital should be allowed to deny them entry solely based on this reason or any other issues with identity proofs;
- (iv) A related issue is when individuals often get their family member admitted in a hospital in one city, but have to travel to another city to look for oxygen or essential drugs and are denied their use because they are to be bought

¹² **Suo Motu vs State of Gujarat**, R/Writ Petition (PIL) No 53 Of 2021

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for an individual admitted in a different city. As was true for the above such rule, this is also unacceptable and should not be allowed;

- (v) Admissions to hospital must be based on need. The Central Government, in consultation with the respective State Governments, must formulate guidelines on the stage at which hospitalization is required so as to ensure that scarce hospital beds are not occupied by persons who do not need hospitalization. This aspect should be based on the advice of medical experts and can be suitably altered given the needs of each State (or regions within the State) and in the course of the experiences gained during the pandemic; and
- (vi) Directions are hereby issued to all States, Union Territories, and all public agencies, to ensure that the above orders are implemented forthwith. The Central, State and Union Territory governments shall issue necessary orders and circulars, incorporating the above directions, within three days, which shall be in force till replaced by an appropriate uniform policy, devised by the central government, statutorily.

D Oxygen allocation and availability

- 24 The Central Government has argued the following:
- (i) By its order dated 11 September 2020, the Ministry of Home Affairs¹³, in exercise of its powers under Section 10(2)(h) of the DMA had constituted an Empowered Group-II as an inter-ministerial body to ensure availability of essential medical equipment and oxygen management;
 - (ii) Medical oxygen is critical to treatment of COVID affected patients. The entire available capacity of oxygen is used for supply for industrial and medical use, which is in the form of Liquid Medical Oxygen¹⁴. The major suppliers for both industrial and medical oxygen are steel plants in the public and private sectors, and private entities;
 - (iii) Oxygen is not produced evenly in India. While some States may be oxygen producing States such as Maharashtra, Rajasthan and Jharkhand; other States/UTs such as Delhi, Goa and Madhya Pradesh, do not have production capacity and rely on supply of oxygen from oxygen producing States;
 - (iv) For an estimation of the required oxygen supply, an Empowered Group I was constituted which categorized patients into three categories:
 - Class I comprising of 80% of the cases which are mild and do not require oxygen;

¹³ "MHA"

¹⁴ "LMO"

- Class II comprising of 17% cases which are moderate and can be managed on non-ICU beds and 50% of these may require oxygen @10L/min; and
 - Class III comprising of 3% of cases which are severe ICU cases requiring approximately 24L/min oxygen.
- (v) On the basis of the categorization provided by Empowered Group I, oxygen requirement of different States on the basis of active cases is being calculated which is around 8462 MT. Based on the trend of active cases, the “doubling rate of cases” is calculated for each State, which implies, the number of days in which COVID cases are likely to double. The number of active cases are projected on the basis of the doubling rate and oxygen requirement is calculated. These projections get changed daily on the basis of real time change;
- (vi) In order to ensure supply of oxygen to all States, a mapping exercise of the sources of supplies with the demand of medical oxygen to the critically affected States was undertaken jointly by the Department of Promotion of Industry and Internal Trade, MoHFW, Ministry of Steel, Petroleum and Explosives Safety Organisation, oxygen manufacturers etc. During the course of the mapping exercise, States were requested to indicate their projections for requirement of medical oxygen based on expected active case load. These projections were to be given as on 20 April, 25 April, and 30 April 2021. The following was the forecast provided by the major States:

S. No.	State	Forecast for requirement for medical oxygen (MT) as on		
		Apr-20	Apr-25	Apr-30
1	Maharashtra	1500	1750	2000
2	Uttar Pradesh	400	650	800
3	Chhattisgarh	215	295	382
4	Karnataka	300	155	111
5	Kerala	89	99	104
6	Delhi	300	349	445
7	Tamil Nadu	200	320	465
8	Madhya Pradesh	445	565	700
9	Rajasthan	125	124	124
10	Gujarat	1000	1050	1200
11	Haryana	180	180	180
12	Punjab	126	82	82
TOTAL		4880	5619	6593

(vii) Based on these projections, an indicative mapping framework was drawn up and approved by an order dated 15 April 2021, which provided the name of the supply point, the State to which supply was allocated and the quantity to be supplied. Subsequently, due to continuous changes in the number of cases and the need for medical oxygen, a revised projection was issued by States for 20 April 2021, which provided:

S. No.	State	Forecast for requirement for medical oxygen (MT) for 20th April		
		Initial	Revised	Remarks
1	Maharashtra	1500	1500	-
2	Uttar Pradesh	400	800	100% increase
3	Chhattisgarh	215	215	-
4	Karnataka	300	300	-

S. No.	State	Forecast for requirement for medical oxygen (MT) for 20th April		
		Initial	Revised	Remarks
5	Kerala	89	89	-
6	Delhi	300	700	133% increase
7	Tamil Nadu	200	200	-
8	Madhya Pradesh	445	445	-
9	Rajasthan	125	147	18% increase
10	Gujarat	1000	1000	-
11	Haryana	180	180	-
12	Punjab	126	126	-
13	Telangana	-	350	-
14	Andhra Pradesh	-	400	-
15	Uttarakhand	-	75	-
TOTAL		4880	5619	

- (viii) Following this, a revised supply plan for medical oxygen to 15 States for meeting their demand was issued by an order dated 18 April 2021. Certain States, such as Delhi, Rajasthan, Punjab, Uttar Pradesh, Uttarakhand and Madhya Pradesh, faced challenges despite this allocation. Issues such as logistical bottlenecks in transportation, incidents of local authorities in disrupting supplies to other states were reported. Due to this, allocation orders were further amended by orders dated 21 April 2021, 22 April 2021, 24 April 2021, 25 April 2021 and 26 April 2021. The MHA also issued orders dated 22 April 2021 and 25 April 2021 under the DMA to direct States/UTs to ensure uninterrupted movement of medical oxygen;
- (ix) The major principles on the basis of which the amendments were made were to: (a) ensure that projected requirement of LMO is allocated as far as possible; (b) allocate sources located within the State or closest to the State while balancing requirements from States which have no/low internal

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manufacturing capacity; (c) ensure feasible transportation; (d) ensure minimum disruptions in existing supply chains;

- (x) As an instance, the allocation summary for 28 April 2021 has been placed on record:

Sl No	State	Production Capacity on 28/04/2021 (MT)	Need of State (MT)	Existing Allocation (MT)	Oxygen lifted by the respective States on 26/04/2021 (MT)
1	Maharashtra	1209.18	1784	1784	
2	Goa	No Bulk Manufacturing Plant	11	11	1389.19
3	Gujarat	847.00	1000	975	
4	Dadra & Nagar Haveli	No Bulk Manufacturing Plant	20	20	904.20
5	Karnataka	625.00	770	802	441.19
6	Madhya Pradesh	No Bulk Manufacturing Plant	649	649	613.82
7	Delhi	No Bulk Manufacturing Plant	470	490	361.90
8	Haryana	246.86	180	232	228.64
9	Uttar Pradesh	244.00	857	857	640.68
10	Punjab	No Bulk Manufacturing Plant	137	177	
11	Chandigarh		20	40	180.38
12	Tamil Nadu	366.00	280	220	396.48

- (xi) After the Central Government procures and allocates the quantity of medical oxygen to each State, it is the State Government's responsibility to arrange transportation to pick up their allotted quantity from the supply point;
- (xii) Given the fact that the mapping exercise has to be continuously updated according to the need of the situation across States, the Central Government also put in an interactive mechanism called the "Virtual Central Control Room" consisting of senior officers of Additional/Joint Secretary rank to monitor and find solutions to any problems that may arise on a real time basis. We have been apprised that the daily allocation of the

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supply of oxygen is sanctioned and uploaded on this virtual room, in which the Chief Secretaries of all States/UTs are members;

(xiii) In addition to the management of supply and demand of medical oxygen, the Central Government has also taken the following steps to ensure augmentation of supply in the country:

(a) Licenses to industrial gas manufacturers: By an order dated 7 April 2020, the Drug Controller General of India¹⁵ allowed licenses to be issued to industrial gas manufacturers for manufacturing medical oxygen within 24 hours of receipt of the application by DCGI;

(b) Enhanced production of LMO in steel plants and by private manufacturers: Steps have been taken to reduce production of other liquid products which are required for manufacturing steel (such as argon and nitrogen) and enhance the capacity of liquid oxygen. This has resulted in immediate enhancement of 293 MT. Additionally, the steel sector has made available the liquid oxygen in its storage tanks (approx. 16,000 MT as on 21 April 2021). Supplies have increased from 1000 MT in the first week of April 2021 to 2600 MT on 21 April 2021. Moreover, private manufacturers have also enhanced production of medical oxygen;

(c) Restrictions on use of industrial oxygen: By an order dated 18 April 2021, the MoHFW restricted industrial use of oxygen. Supply of oxygen for all industrial use was completely prohibited on 21 April 2021, except for certain industries such as ampoules and vials; pharmaceuticals;

¹⁵ "DCGI"

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petroleum refineries; nuclear energy facilities; and oxygen cylinder manufacturers. These have added 1000 MT of additional oxygen;

(d) Augmentation in availability of tankers: India has 1224 oxygen tankers (16732 MT capacity) and efforts are being made to increase this capacity to 2000 tankers through conversion of nitrogen and argon tankers and import of 138 cryogenic tankers;

(e) Commissioning of PSA plants: Pressure Swing Absorption¹⁶ is a technology to generate oxygen at a local level. PSA plants established in hospitals enable self-sufficiency in generation of oxygen. MoHFW is in the process of commissioning 162 PSA Plants (154 MT capacity).

The following statistics have been furnished :

Number of plants installed:	38
Number of plants to be installed by 30 April 2021	21
Number of plants to be installed by 31 May 2021	105
Number of plants to be installed by 30 June 2021 ¹⁷	51
Number of PSA Plants for district headquarters (under planning)	500

(f) Import of medical oxygen: A global tender was floated to import 50,000 MT of medical oxygen to be supplied in 90 days and quotations have been received. As an interim measure, quotations from bidders were called within 24 hours as to the quantities they could offer, prices etc. Orders have been placed with 2 foreign suppliers, i.e., SSB Cryogenic Equipment Ltd. for 200 MT and Gulf Industrial Gases Abu

¹⁶ "PSA"

¹⁷ As per the affidavit dated 23 April 2021, the UOI has stated that "a further 105 plants will be installed by 31.05.2021 and thereafter increasing to 156 plants by 30.06.2021."

Dhabi for 1800 MT. Another order is also being placed with M/s Ultra-Pure Gases India for import of 500-1500 MT;

(g) Augmentation of availability of cylinders: 1,02,400 oxygen cylinders were procured in April and May 2020 and distributed to States. Orders for additional 1,27,000 cylinders were placed on 21 April 2021. The Central Government proposes to address the additional demand through regulated portable oxygen system technology;

(h) Setting up of jumbo container based COVID hospitals using gaseous oxygen: Apart from LMO, the gaseous oxygen production capacity in the steel sector is 43,000 MT per day against which 26,000 MT per day is being produced. Two private entities, AMNS and JSW are setting up "Jumbo" COVID centres with 1000 bed oxygen facilities in Hazira, Vijayanagar and Dolvi using gaseous oxygen; and

(i) Transportation by Air & Rail: Railways are being used for long distance transport of tankers through 'roll on roll off' service and an "Oxygen Express" - a double engine train which gets a green corridor - is being run from supply point to destination. As an instance, the first rake with 7 empty tankers reached Mumbai from Vizag to transport 105 MT from RINL Vizag to Kalamboli. In addition to this, defence aircraft for carrying empty tankers to supply point are being deployed. However, it is technically not possible to bring in oxygen filed tankers in an aircraft.

25 During the course of the hearing, the Solicitor General has also sought to lay down the facts and figures pertaining to production and supply of oxygen, daily supply to States and challenges faced in supply chain logistics before the

Court by means of a power point presentation. We note the submission of the Solicitor General that the figures given in the power point presentation are revised on a daily basis and that the presentation is not to be treated as a submission made on oath by the Solicitor General, which may give rise to a cause of action for litigation in future either before this Court or the High Courts. Ms Sumita Dawra, Additional Secretary, Department of Promotion of Industry and Internal Trade, Ministry of Commerce and Industry, who is one of the senior administrative officers in charge of oxygen procurement and supply coordination, has given an overview of these issues and made a presentation before us. We would like to record our appreciation for the contribution made by Ms Dawra and her team, who despite being infected by the COVID-19 virus, has continued to work and manage the supply of medical oxygen that the country so desperately needs today. It is through the earnest contribution of officers such as Ms Dawra, who are working round the clock, that the country is able to deal with the storm created by one of the worst humanitarian crises we have seen.

26 Based on the above facts and figures, the Solicitor General has stated that there is no dearth of oxygen supply in the country as on date and steps are being taken continuously to augment the supply of oxygen. Having said that, the Solicitor General has also admitted that there has been a shortage of supply to certain States and has attributed this shortage to various factors including the failure of State Governments to lift the allocated quantity of oxygen from the supply point; transportation bottlenecks caused by inter-State movement of tankers; and technical failure of certain plants leading to reassessment of allocation on a real time basis.

27 Submissions have also been made on the issue of supply of oxygen by Mr Rahul Mehra, learned Senior Counsel appearing for the Government of National Capital Territory of Delhi¹⁸. Mr Rahul Mehra submits that the GNCTD is facing an acute shortage of the supply of oxygen as it had been allocated a substantially lower quantity of oxygen as against its projected demand. Mr Mehra pointed out that initially as on 15 April 2021, the projected demand of GNCTD for 20 April 2021 was 300 MT/day, for 25 April 2021 it was 349 MT/day, and for 30 April 2021 it was 445 MT/day. However, due to a surge in cases, the projected demand was revised by GNCTD on 18 April 2021 to 700MT/day and this was immediately communicated to the Central Government. Despite the increase in projected demand, the supply of oxygen to GNCTD has continued in terms of the allocation order dated 25 April 2021, in which 490 MT/day were allocated. As against this as well, the manufacturers have only been able to supply 445 MT/day. Mr Mehra has clarified that as on the date of the hearing their demand was 700MT/day, however their projected demand for the coming days is stated to be 976 MT/day as the GNCTD has planned an increase in medical infrastructure, including beds with oxygen cylinders and beds for patients in intensive care unit.

28 Opposing his submission, the Solicitor General and Ms Dawra stated that no revised projections have been received from GNCTD till date. The Solicitor General has also sought to highlight that the government of GNCTD has failed to offtake the allocated quantity of oxygen from the supply point.

29 Having heard the submissions of both counsels on the issues pertaining to supply of oxygen to GNCTD, we note that the Central Government (on page 63)

¹⁸ "GNCTD"

in its affidavit dated 23 April 2021 has admitted that the projected demand for GNCTD as of 20 April 2021 had increased by 133% from 300 MT/day to 700 MT/day. According to the figures of allocation given in the affidavit dated 23 April 2021 and the presentation given by Ms Dawra, the existing allocation of GNCTD remains at 490 MT/day. This situation must be remedied forthwith. The situation on the ground in Delhi is heart rending. Recriminations between the Central Government (which contends that GNCTD has not lifted its allocated quantity) and GNCTD (which contends that despite its projected demand the quantity allocated has not been enhanced) can furnish no solace to citizens whose lives depend on a thin thread of oxygen being available. On the intervention of the Court during the hearing, the Solicitor General states that he has instructions to the effect that GNCTD's demand of medical oxygen will be met and that the national capital will not suffer due to lack of oxygen. We issue a peremptory direction in those terms. In the battle of shifting responsibility of supplying/off-taking of oxygen, lives of citizens cannot be put in jeopardy. The protection of the lives of citizens is paramount in times of a national crisis and the responsibility falls on both the Central Government and the GNCTD to cooperate with each other to ensure that all possible measures are taken to resolve the situation. Learned Senior Counsel for GNCTD has assured the court after taking instructions at the 'highest' level that the issue will be resolved completely in a spirit of co-operation. During the course of the hearing, the Solicitor General has assured that henceforth he will ensure that the deficit of oxygen is rectified and supply is made to the GNCTD according to their projected demand (which may be revised in the future) on a day by day basis. We accept his submission and

direct compliance within 2 days from the date of the hearing, that is, on or before midnight of 3 May 2021.

30 With regard to the issue of the supply and availability of medical oxygen for the entire country, we have noted that efforts are being made to augment the availability of oxygen. While the Central and State Governments are in the process of managing the supply of oxygen, at the same time, it is critical that a buffer emergency stock of oxygen is created so that in the event that the supply chain is disrupted to any one or more hospitals in an area for any reason, the buffer or emergency stocks can be used to avoid loss of human lives. These emergency stocks must be so distributed so as to be easily accessible without delay in every local area. We have also seen the situation that has developed in the last 24 hours in Delhi where patients, including among them medical professionals, died because of the disruption of supplies and the time lag in the arrival of tankers. This deficit shall be rectified immediately by the Central Government by creating buffer stocks and collaborating with the States through the virtual control room on a 24 by 7 basis. In view of the deaths which are being caused daily by the disruption of supplies, this direction is more crucial than ever. We therefore, direct the Central Government in collaboration with the States to prepare a buffer stock of oxygen to be used for emergency purposes to ensure supply lines continue to function even in unforeseen circumstances. The location of the emergency stocks shall be decentralised so as to be immediately available if the normal supply chain is disrupted to any hospital for any reason. The emergency stocks shall be created within the next four days. The replenishment of the emergency stocks will also be monitored on a real time basis through the

virtual control room in active consultation with each state/UT. This is in addition to the day to day allocations.

31 In addition to the above, we direct the Central Government to consider the following suggestions, which may assist in increasing the availability of oxygen and ensure transparency of demand-supply management, and provide a clarification to this Court:

- (i) We understand that the Virtual Central Control Room of the Central Government displays the allocation of supply of oxygen by the Central Government to each State/UT. By extension of this, a mechanism for displaying real time updates of supply of oxygen from each State to hospitals in each district, along with the remaining stock of oxygen with the hospitals may be maintained and shared with the citizens to ensure transparency. This will also ensure that citizens can easily identify the hospitals where medical aid can be availed;
- (ii) The government shall clarify the steps being taken on planning on the use of oxygen concentrators to reduce the demand of LMO, such that LMO is needed only for critical patients. A comprehensive plan on augmenting the production/import of these oxygen concentrators may be considered;
- (iii) The expected supply of oxygen/containers to be received from outside India should be suitably augmented to cater to anticipated increases in the demand and shortfall of domestic availability. Pending the early finalization of the global tender a decision may be taken on the need to continue imports to bridge the gap in availability; and

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- (iv) A review shall be made of any restrictions on inter-State travel of trucks or tankers carrying oxygen/other medical aid equipment (such as GST related issues, documentation) which might cause a hindrance in their movement.

The Central Government may consider implementing a system to track and map the supply tankers which would allow better management of resources and allow diversion of resources from one State to the other in case of emergencies.

E Vaccines

32 The previous order of this Court dated 27 April 2021 directed the Central Government to clarify, *inter alia*: (i) the projected availability of vaccines and proposed steps to boost supply and distribution; and (ii) the vaccine pricing and distribution *among* states. Upon perusing the affidavits filed by the Central Government and after having the benefit of oral arguments of the Solicitor General, we have arrived at the following understanding on the two broad issues outlined above. We would once again re-iterate that we do not attempt to delve into the role of the executive in designing policy choices. We are merely seeking to enter into a dialogue with the relevant stakeholders in order to ensure probity and transparency of the measures underway. We are cognizant that it is ultimately up to the executive to frame and implement policies that it deems appropriate, with the topmost regard to public interest.

E.1 Vaccine capacity and disbursal

33 The Central Government has apprised us of its constitution of a National Expert Group on Vaccine Administration for COVID-19¹⁹ on 7 August 2020 and operationalization of the immunization programme from December 2020. It was further stated that as of 26 April 2021, over 13.5 crore vaccine doses (approx. 9% of the Indian population) have been administered to Frontline Workers, Healthcare Workers and persons who are 45 years of age and higher in the 3 Phases of immunization. It was submitted that these vaccines have been

¹⁹ "NEGVAC"

centrally procured and administered free of cost to the abovementioned groups who were identified based on specific vulnerabilities and a higher mortality rate on account of the COVID-19 infection.

34 On 20 April 2021, the Central Government rolled out a revised strategy of COVID-19 vaccination for all persons over 18 years of age, with effect from 1 May 2021. This new age group consists of approximately 59 crore people, which would require 122 crore vaccine doses under the current two-dose vaccine regime of Covishield and Covaxin which have been authorized for emergency use in India. This revised strategy enables vaccine procurement by State Governments and private hospitals, purportedly for accelerating the immunization programme which is critical to curb the pandemic. In response to the query of this Court on the necessity of the revised strategy, the Central Government furnished the following justification:

"During the ongoing consultation with the states, demands/concerns were raised by the various State Governments to expand the scope of vaccination drive to include the beneficiaries beyond the priority groups identified by NEGVAC as approved by Central Government. As a matter of co-operative federalism, it was felt necessary to allow play in the joints and to de-centralize vaccine procurement and to enable the States to expand vaccination drives to other groups between the age of 18-44 years. However, **since the priority group as identified by Union of India (which had more vulnerability) was not fully vaccinated, it was considered imperative to carry out two drives separately i.e. in a decentralized manner to achieve higher efficiency and reach.** Thus the States were given a participatory role to undertake the procurement of vaccine and for vaccination of any other 'groups identified drive' for the 18-44 age group. This would also keep the existing drive of critical groups unobstructed as the 50 percent of the vaccines procured through the G01 channel would continue to support and provide free of cost vaccine to the most vulnerable age groups of 45 years plus in the country health care workers and frontline worker

identified by the Union of India who were entitled to get vaccinated under Phase II.”

(emphasis supplied)

35 In response to the queries of the Court on how the supplies of vaccines will be allocated between various states if each State Government is to negotiate with vaccine producers, the Central Government has furnished the following justification in order to iron out the inequities between States:

“For the remaining 50% non-government of India channel, the states and the private hospitals are free to procure vaccine for 18-44 years population, however, to have an equitable distribution of vaccine across the country, states have been allocated the available vaccine quantity in proportion to the population between 18-44 years of age of the respective state so as to ensure equitable distribution of vaccine as there is a possibility of some states having better bargaining power due to geographical advantage etc.”

(emphasis supplied)

36 During the course of the hearing, this Court has expressed its reservations *prima facie* on the validity of the revised policy under which the states and private hospitals are to procure 50% of the vaccines in order to immunize persons in the 18-44 years age group. For one thing, even this age group would consist of persons who suffer from vulnerabilities. Once the vaccination programme has been opened up for persons other than the 45 plus age group, it would not be logical to impose the obligation to source vaccinations for the 18-44 age group on the State Governments. This will, *inter alia*, leave each State Government to negotiate supply schedules, delivery points and other logistical arrangements with the manufacturers. At present, there are only two manufacturers for the authorized vaccines (with one other vaccine - Sputnik V, in the process of

manufacture). The available stock of vaccines is not adequate to deal with the requirements of both the categories. The Central Government must take the responsibility of providing guidance to every State on the quantities to be supplied to each State, the vaccine(s) being allocated, the period of delivery, and the number of persons who can be covered for vaccination, among other details. Leaving the State Governments to negotiate directly with manufacturers will produce chaos and uncertainty. The object of vaccinating the 18-44 age group cannot be achieved in the absence of stocks being available.

37 Besides the above issues, the Central Government is directed to clarify the following issues in order to ensure the protection of the fundamental rights to equality and to life and personal liberty for all persons who will be eligible to take the vaccine from 1 May 2021:

- (i) Whether the Central and State Governments have introduced any initiatives for ensuring the immunization of persons who do not have access to digital resources as otherwise the mandatory requirement of registration over the Co-WIN digital portal for persons in the age group of 18-44 years will deprive a large class of citizens of vaccination;
- (ii) Since the Central Government commits to vaccinating persons over 45 years, free of cost, in view of their vulnerability, whether walk-in facilities for vaccination will continue for these persons after 1 May 2021;
- (iii) Whether the Central or State Governments propose to undertake targeted vaccination drives for persons who are providing on-ground assistance during the second wave of the pandemic - such as crematorium workers,

who were not considered as Frontline or Healthcare workers for Phase 1 of the vaccination drive;

- (iv) Whether, and if so what, steps being undertaken by INYAS, the nationwide mass awareness campaign for COVID-19 vaccination, for ensuring outreach in rural areas and socio-economically underprivileged sections of society including the possibility of using mobile vans, vehicles and railways to vaccinate such people as well as those living in remote areas, near their doorsteps so as to minimize their travel and potential infection with COVID-2019. Efforts must also be made that a lack of an identity proof does not create a hindrance in the process of immunization of all individuals, specifically, the underprivileged;
- (v) Whether the Central government will revisit its policy by procuring 100% of the doses which can then be equitably disbursed to the State Governments; and
- (vi) Since the vaccine administration is now to be a shared responsibility of the Union and the States, the Central Government and the State Governments shall provide- (a) a breakup of the current and projected availability of vaccine stocks for the next 6 months; and (b) a timeline for achieving immunization of the newly eligible 59 crore persons who are aged between 18-44 years.

These issues are of vital importance, since vaccination appears to be one of the most important strategies to combat further spread of the pandemic, and would also provide a measure of security and assure the people about their health and well-being.

E.2 Vaccine pricing

38 Since the advent of the revised rollout strategy with effect from 1 May 2021, only persons aged 45 years and above are guaranteed a free vaccine. The reason of higher efficiency and speed has been furnished as a justification for enabling State Governments and private hospitals to directly procure vaccines. We have come to understand that a few State Governments have committed to free immunization under the revised strategy. On specific enquiry on the rationale in regard to the differential pricing for procurement by the Central Government and the State Governments, the Central Government has furnished the following justification:

"It is submitted that liberty to decide prices on arm's length basis by and between the State Government and hospitals is based on the concept of creating an incentivized demand for the private vaccine manufacturers in order to instill a competitive market resulting in increased production of vaccines and market driven affordable prices for the same. Simultaneously, the free vaccination by the Central Government for above referred priority age groups would continue and it is always open for each State Government either to offer free vaccination or subsidise it for the additional identified earmarked priority group identified by the State Governments [age 18-44 years].

63. The new strategy was devised after multiple Inter-Ministerial teams were deputed by Govt. of India to various manufacturing sites to understand their requirement and to provide pro-active and customized support to significantly augment vaccine production capacities [which is the prime priority of the Central Government at this juncture], in the form of advance payments, facilitating more sites for production etc. **This approach, on the one hand, incentivizes vaccine manufacturers to rapidly scale up their production and on the other hand, it would also attract new vaccine manufacturers. It would make pricing, procurement and administration of vaccines more flexible and competitive and would further ensure augmented vaccine production as well as wider availability of vaccines in the country."**

(emphasis supplied)

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39 *Prima facie*, there are several aspects of the vaccine pricing policy adopted by the Central government which require that policy be revisited. All vaccines, whether in the quantity of 50% purchased by the Central Government or the remaining 50%, are to be used for vaccinating citizens. The end use is the same. The Central Government proposes to purchase half of the total quantity falling within its fifty per cent quota while for the rest, the manufacturers would declare in advance the price to be fixed, allowing the State Governments to negotiate their terms. As of date, the manufacturers have suggested two different prices, a lower price which is applicable to the Central Government and a higher price which is applicable to the quantities purchased by the State Governments. It is likely that compelling the State Governments to negotiate with manufacturers on the ground of promoting competition and making it attractive for new vaccine manufactures will result in a serious detriment to those in the age group of 18 to 44 years, who will be vaccinated by the State Governments. The social strata of this age group also comprises persons who are *Bahujans* or belong to other under privileged and marginalized groups, like many in the other population age groups. They may not have the ability to pay. Whether or not essential vaccines will be made available to them will depend upon the decision of each State Government, based on its own finances, on whether or not the vaccine should be made available free or should be subsidized and if so, to what extent. This will create disparity across the nation. The vaccinations being provided to citizens constitute a valuable public good. Discrimination cannot be made between different classes of citizens who are similarly circumstanced on the ground that while the Central government will carry the burden of providing free vaccines for the 45 years and

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above population, the State Governments will discharge the responsibility of the 18 to 44 age group on such commercial terms as they may negotiate. *Prima facie*, the rational method of proceeding in a manner consistent with the right to life (which includes the right to health) under Article 21 would be for the Central Government to procure all vaccines and to negotiate the price with vaccine manufacturers. Once quantities are allocated by it to each State Government, the latter would lift the allocated quantities and carry out the distribution. In other words, while procurement would be centralized, distribution of the vaccines across India within the States/UTs would be decentralized. While we are not passing a conclusive determination on the constitutionality of the current policy, the manner in which the current policy has been framed would *prima facie* result in a detriment to the right to public health which is an integral element of Article 21 of the Constitution. Therefore, we believe that the Central Government should consider revisiting its current vaccine policy to ensure that it withstands the scrutiny of Articles 14 and Article 21 of the Constitution.

40 In light of the justification offered for non-interference in the prices that are set by the manufacturers, irrespective of their variance from the prices for procurement of the Central Government, we would like to seek the following clarifications:

- (i) Whether any other alternatives were considered by the Central Government for ramping up the immunization drive in India, particularly in light of its initial strategy of a centralized free immunization drive;

- (ii) The methodology which the Central Government was envisaging to procure adequate vaccine doses for the population prior to the revised strategy which was announced amidst the second wave of COVID-19; and
- (iii) Whether any studies and figures were relied upon in order to arrive at the conclusion that decentralized procurement would spur competitive markets to incentivize production and eventually drive down the prices of the vaccines. Whether these studies are of relevance in a pandemic when vaccines are a scarce and essential commodity which is being produced by a limited number of manufacturers for a limited number of vaccines.

41 The Central Government has submitted that the Finance Ministry has sanctioned a credit of Rs 3000 crores for Covishield manufacturer - Serum Institute of India²⁰ and Rs 1500 crores to Covaxin manufacturer - Bharat Biotech. Additionally, another Rs 65 crores is stated to have been provided to Bharat Biotech's production center at Bangalore. In bolstering its argument for augmentation of vaccine production, the Central Government has provided the Court with further information on advance funding (of unspecified amounts) that is being provided to R&D and manufacturing facilities. In light of this investment, the Central Government should consider revisiting its policy bearing in mind what has been stated above, the following issues and other relevant information:

²⁰ "SII"

- (i) Whether, and if so, the Finance Ministry or any other funding organization of the Government of India have made any grants/sanctions to Bharat Biotech and the SII in the past, like the current infusion of Rs 1500 crores and Rs 3000 crores, respectively. If so, breakup and corelation with the total cost of development and production of the two vaccines;
- (ii) Whether the current procurement prices for the Central Government account for infusion of funds for production, infrastructure and other aid provided by it. If so, the basis on which the same benefit is denied to procurement by State Governments which equally service the needs of citizens; and
- (iii) The full extent of direct and indirect grant/aid provided for research, development and manufacture of all existing vaccines and future vaccines that it proposes to authorize. For instance, the Central Government has submitted in its affidavit that the Department of Biotechnology has facilitated the trials for Sputnik V.

F Potentiality of Compulsory Licensing for vaccines and essential drugs

42 Several drugs that are at the core of the COVID treatment protocol are under patents in India including Remdesivir, Tociluzumab and Favipiravir. On 2 October 2020, a communication was issued by the UOI, along with South Africa, to the Council for Trade-Related Aspects of Intellectual Property which stated that there were several reports about intellectual property rights hindering timely

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provisioning of affordable medical products to patients²¹. The communication also reported that some members of the World Trade Organization had carried out urgent amendments to their national patent laws to expedite the process of issuing compulsory/government use licenses.

43 In India, the patent regime is governed by the Patents Act, 1970²², Section 92 of which envisages the grant of a compulsory license, *inter alia*, in circumstances of national emergency and extreme urgency. Once a declaration of national emergency is made, and the relevant patents notified, any person interested in manufacturing the drug can make an application to the Controller General of Patents who can then issue a compulsory license. The patentee would be paid a reasonable royalty as fixed by the Controller General of Patents. Further, under Section 100 of the Patents Act, the Central Government can authorize certain companies to use any patents for the “purpose of the government”. Indian companies can begin manufacturing the drugs while negotiating the royalties with the patentees. If the Central Government or its authorized company is not able to reach an agreement with the patentee, the High Court has to fix the reasonable royalty that is to be paid to the patentee. Another alternative is for the Central Government to acquire the patents under Section 102 from the patentees. If the Central Government and the patentee is not able to reach a consensus on the price of the patents, it is up to the High Court to fix the royalty. Additionally, under Section 66 of the Patents Act, the Central Government is also entitled to revoke a patent in the public interest.

²¹ Council for Trade-Related Aspects of Intellectual Property Rights, Waiver From Certain Provisions Of The Trips Agreement For The Prevention, Containment And Treatment Of Covid-19, Communication From India And South Africa, IP/C/W/669, 2nd October, 2020, available at <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>

²² “Patents Act”

44 The utilization of these flexibilities has also been detailed in the Trade Related Aspects of Intellectual Property Rights Agreement²³. Even as TRIPS obliges countries to ensure a minimum level of patent protection, it creates a permissive regime for the carving out of exceptions and limitations that further public health objectives²⁴. This is evident from a conjoint reading of Articles 7, 8, 30 and 31 of TRIPS. Article 7 outlines the objectives of the TRIPS as being to ensure the effective enforcement of intellectual property in a way that, *inter alia*, is ‘conducive to social and economic welfare’. Article 8 gives member countries the freedom to take measures that protect public health and nutrition. Article 8(2) allows for the taking of TRIPS-compatible measures aimed at preventing the abuse of intellectual property rights. Articles 30 and 31 deal with exceptions to the rights of patent owners, by allowing grant of compulsory licenses. It leaves countries with significant breathing space to determine how the compulsory licensing or government-use levers can be triggered. While such determinations must be made on the individual merits of each case²⁵, the aforesaid caveat does not apply when the compulsory license grant is for national emergency, extreme urgency or public non-commercial use²⁶.

45 According to the 2001 Doha Declaration, TRIPS should be interpreted in a manner supportive of the right of members to protect public health and to promote access to medicines²⁷. It recognizes the right of WTO members to use the full extent of the TRIPS flexibilities to secure this objective. Para 5(b) of the Doha

²³ “TRIPS”

²⁴ Report of the United Nations Secretary-General’s High-Level Panel on Access to Medicines Promoting Innovation and Access to Health Technologies, (United Nations Secretary-General, 2016), p. 16.

²⁵ TRIPS Agreement, Article 31(a).

²⁶ TRIPS Agreement, Article 31(b).

²⁷ World Trade Organization, ‘Ministerial Declaration of 14 November 2001’ (November 2001) WT/MIN(01)/DEC/1, 41 ILM 746, para 4.

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Declaration provides the freedom to each member to grant compulsory licenses and to determine the grounds on which the licenses are granted. Para 5(c) leaves it up to each nation to determine what constitutes a national emergency or extreme urgency. In the context of the COVID-19 pandemic, we note that several countries such as Canada and Germany have relaxed the legal regimes governing the grant of compulsory licenses²⁸.

46 Whether and if so, the extent to which these provisions should be utilized is a policy decision for the Central Government. We have flagged the issue for its consideration. We have only outlined the legal framework within which the Central Government can possibly consider compulsory licensing and government acquisition of patents. The Central Government is free to choose any other course of action that it deems fit to tackle the issue of vaccine requirements in an equitable and expedient manner, which may involve negotiations with domestic and foreign producers of vaccines. We clarify that it is up to the Central

²⁸ 'COVID-19 IP Policy Tracker' (WIPO, 16 July 2020), available at <https://www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/access>.

Government to choose the best possible measures it can undertake during the current crisis keeping in mind that public interest is of paramount importance.

G Supply of Essential Drugs

G.1 Submissions in the Central Government's Affidavits

47 In relation to the broad issue of "Supply of Essentials", in its affidavit dated 23 April 2021 and additional affidavit 29 April 2021, with respect to Remdesivir, the UOI urged that:

- (i) Remdesivir is a patented drug which is being manufactured in India under licensing agreements between the patent holder, M/s Gilead, a US based company and seven Indian companies. Under such agreements, these Indian companies are allowed to manufacture Remdesivir for distribution;
- (ii) In its affidavit dated 23 April 2021, it was submitted on behalf of the Central Government that the current production is about 74 lakhs vials per month and once the additional manufacturing sites of the seven manufacturers become operational by May 2021, the production capacity will increase to 90 lakhs vials per month. In its additional affidavit dated 29 April 2021, the Central Government has submitted that as on 23 April 2021, the production capacity has increased to 1.03 crore vials per month;
- (iii) The Central Government allocated 11 lakhs vials of Remdesivir to nineteen States with a high case load between 21 to 30 April through a letter issued on 21 April 2021. This allocation was revised and expanded to all States and UTs through a letter issued on 24 April 2021;

- (iv) The Central Government has directed the States to appoint nodal officers to ensure unrestricted and timely movement of Remdesivir. A control room has been set up in this regard by the National Pharmaceutical Pricing Authority²⁹ which is monitoring supplies as allocated. A helpline has been set up by NPPA and manufacturers have been directed to address the hindrances in the movement of the drug. A WhatsApp group with nodal officers has also been created to enable coordination and officials of MHA, NPPA and CDSCO are also part of the group;
- (v) Remdesivir, its Active Pharma Ingredients³⁰ and formulations have been placed under export ban since 11 April 2021;
- (vi) The Ministry of Finance has issued a notification on 20 April 2021 exempting customs duty on the Remdesivir injection, and API of Remdesivir and Betacyclodexterin, which are used in the manufacture of the injection. All the SEZ/EOU manufacturing units of M/s Mylan and M/s Honous Lab, who are manufacturing Remdesivir on behalf of some of the seven manufacturers have also been directed to start manufacturing Remdesivir for domestic supply;
- (vii) CDSCO has directed all State Drug Controllers on 10 April 2021 to conduct a special investigation drive to prevent hoarding and black-marketing of Remdesivir in the country. DCGI and State Drug Controllers have been taking stringent action against such activities and enforcement action has been taken in thirty-four cases across the country;

²⁹ "NPPA"

³⁰ "API"

- (viii) MHA has issued an advisory on 22 April 2021 to States and Union Territories to facilitate smooth movement of supplies. A “Covid Drug Management Cell” consisting of the Department’s Senior Officers and others has been constituted on 26 April 2021 to oversee and identify common concerns raised by States in relation to Remdesivir;
- (ix) NPPA has revised the maximum retail price of a 100 mg/vial of Remdesivir to Rs 3500; and
- (x) The Central Government is also looking at the possibility of importing Remdesivir.

48 The UOI made the following submissions on the availability of Tociluzumab injections:

- (i) Tociluzumab is manufactured by a Swiss Company, M/s Roche, which does not have any manufacturing facility in India or any agreements with domestic pharma companies to manufacture the drug. It is imported in the country by Cipla. India is completely dependent on imports;
- (ii) It is listed as an investigational therapy drug (off-label) under the National Clinical Management Protocol for COVID-19 for severe cases. There are domestically produced alternatives which are equivalent to or better than Tociluzumab such as itulizumab, dexamethasone and methyl prednisolone. However, an incorrect public perception has been created that only Tociluzumab can treat the inflammatory burst condition in COVID-19 patients since it is an imported drug. This has led to the acute shortage in the availability of the drug and has created public panic; and
- (iii) The supply of Tociluzumab is being monitored by NPPA and CDSCO.

49 The UOI has made the following submissions on the availability of other drugs:

- (i) The National Clinical Management Protocol for COVID-19 does not include Favipiravir (popularly known as Fabiflu) due to insufficient peer reviewed evidence to substantiate its use in mild to moderate cases of COVID-19. However, it is being prescribed by certain doctors. The clinical management protocol is a dynamic document which is reviewed periodically and is subject to further evaluation based on medical research and evidence that comes up in future; and
- (ii) On 24 April 2021, Department of Pharmaceuticals³¹, NPPA and DCGI had reviewed the production and supply of other drugs such as Favipiravir, Enoxaparin, Ivermectin, Methylprednisolone, Paracetamol and Hydroxychloroquine. A meeting was conducted on 25 April 2021 by NPPA and DCGI with manufacturers to review stock position, availability and production plans.

G.2 Recommendations

50 In respect of the essential drugs, this Court has been informed that the Central Government is taking steps to augment the production of Remdesivir. It has been brought to our notice that seven Indian companies are manufacturing this drug under a licensing agreement with a US based company, M/s Gilead. The current production capacity as on 23 April 2021 is noted to be at 1.03 crores vials per month. The Central Government should provide us with the details of the actual rate of production and a breakup of demand for the drug from different

³¹ "DoP"

States. Further, while it has been submitted on behalf of the Central Government that it is allocating the stocks based on a rational criterion of equitable distribution keeping in mind the existing constraints on the availability of the drug, this Court should be provided with details of the methodology used for such allocation.

51 We have been informed by the Central Government in its affidavit that NPPA has revised the maximum retail price of Remdesivir to Rs 3500. However, it has come to our notice that several other drugs which are being prescribed by doctors for treating COVID-19 patients like Favipiravir, Tociluzumab, Enoxaparin, Ivermectin, Methylprednisolone, Paracetamol and Hydroxy-chloroquine are being priced at exorbitant rates creating issues of access and affordability. While this is not a direction of this Court, the Central Government can consider invoking its statutory powers under paragraphs 19 and 20 of the Drugs Price Control Order, 2013. Under paragraph 19³² of the Drugs Price Control Order, 2013 the Government in extraordinary circumstances, if it considers necessary in public interest, can fix a ceiling price or retail price of the drug for a certain period. COVID-19 is a crisis of an unprecedented nature and qualifies as an extraordinary circumstance. It will be in public interest to ensure that the price of essential drugs is fixed in such a manner that it is available even to the most marginalized sections of the society. The Government can even monitor the prices of the drugs under paragraph 20³³ of the Drugs Price Control Order, 2013

³² "19: Fixation of the Ceiling Price Under Certain Circumstances: Notwithstanding anything contained in this order, the Government may, in case of extraordinary circumstances, if it considers necessary to do so in public interest, fix the ceiling price or retail price of any drug, as it may deem fit and where the ceiling price or retail price of the drug is already fixed and notified, the Government may allow an increase or decrease in the ceiling price or the retail price, as the case may be, irrespective of annual wholesale price index of that year."

³³ "20: Monitoring the Prices of Non-Scheduled Formulations: (1) the Government shall monitor the maximum retail prices (MRP) of all the drugs, including the non-scheduled formulations and ensure that no manufacturer increases the maximum retail price of a drug more than ten percent of maximum retail price during preceding twelve months and where the increase is beyond ten percent of maximum retail price, it shall reduce the same to

and ensure that no manufacturer increases the prices of the drugs by more than 10% of the maximum retail price during the preceding 12 months and where the increase is beyond 10% of the maximum retail price, it can oblige the manufacturer to reduce it to the level of 10% for the next 12 months.

52 The Central Government has submitted that it plans to import Remdesivir. It can also consider importing other essential drugs to meet the immediate demand of the drug while the production is ramped up. We hasten to clarify that this does not constitute a direction of this Court and ultimately this decision falls under the domain of the executive.

53 We note that there are certain medicines which are being prescribed by doctors which are not mentioned in the National Clinical Management Protocol for COVID-19 like Favipiravir. However, since these medicines are being prescribed by doctors, people are facing significant inconvenience in obtaining them due to their shortage in certain parts of the country. The Central Government should consider whether the production of such medicines should be augmented to meet the demand or instructions should be given to the doctors to not recommend such medicines unless they have been included in the national protocol.

54 It has been submitted on behalf of the Central Government that on 24 April 2021, DoP, NPPA and DGCI reviewed the production and supply of drugs such as Favipiravir, Enoxaparin, Ivermectin, Methylprednisolone, Paracetamol and Hydroxy-chloroquine. The supply of Remdesivir and Tociluzumab is already under the consideration of the Central Government. A meeting was also held on

the level of ten percent of maximum retail price for next twelve months. (2) The manufacturer shall be liable to deposit the overcharged amount along with interest thereon from the date of the increase in price in addition to the penalty."

25 April 2021 by DoP, NPPA and DGCI with the manufacturers to review stock position, availability and production plans. The Central Government should provide details of estimated demand of essential drugs mentioned above, production capacity, existing stocks, details of allocation and supply of such drugs.

55 As discussed in **Section F**, the Central Government can also consider using its powers under Sections 92, 100 or 102 of the Patents Act to increase production of essential drugs to ensure that it is commensurate to the demand. The Central Government's affidavit testifies to existence of capacity of public sector organizations and institutes, which can assist in augmenting production of various drugs and formulations. The utilization of these capabilities to augment production, once licensing is resorted to, will be in the interests of the general public. This Court is further of the opinion that *prima facie* the present circumstance warrant the government's examination of its the extraordinary powers, meant to be used in extreme situations, such as the current pandemic, for fixing drug prices, be it vaccines, or patented formulations, having regard to the provisions of the Drugs and Cosmetics Act, 1940 and other provisions³⁴. We are cognizant that invocation of the above provisions, if any, is ultimately a policy decision of the Central Government and may encompass negotiations with the concerned stakeholders. We hope that the Central Government will adopt a route that best serves the public interest.

³⁴ Paragraph 3 and 19 of the Drugs Price Control Order, 2013

G.3 Black Marketing

56 This Court would like to take judicial notice of the fact that several critical drugs, used to treat COVID-19, such as Remdesivir and Tocilizumab, are being sold at significantly inflated prices or in fake form. This is a condemnable attempt to exploit people's misery and profit from their helplessness.

57 In order to clamp down on this practice, the Central Government can consider constituting a special team to identify and prosecute those who: (a) sell medical grade oxygen/COVID-19 medicines at exorbitant prices; and (b) sell fake substances and recover the concerned substances. A protocol for ambulances must also be evolved to avoid citizens being exploited by extracting unconscionable charges. The Central Government can consider creating a platform for easy reporting and redressal of such cases.

H Recommendations for augmenting healthcare workforce

58 It is common knowledge that a large number of medical, nursing and pharmacy students, who graduated in 2020 and would be in the process of graduating in 2021, would be available to augment the workforce in the health sector. The Central Government should, we feel, look into this aspect, and ensure the optimal manner of utilization of their services, regard being had, of course, to their safety and well-being.

59 The Central Government should also consider using health care workforce available with the armed forces and para military forces for the purpose of vaccination.

I Epilogue

60 The World Health Organisation³⁵, while discussing the rapid spread of COVID-19 has not only labelled it an epidemic but also an “infodemic”, due to the overabundance of information on the internet, which was riddled with misinformation and disinformation³⁶. This highlights the key role internet and technology currently has in all our lives, as the COVID-19 pandemic rages on. Indeed, the WHO recently also conducted a study to understand how individuals between the ages of 18-40 years dealt with the ongoing pandemic using social media³⁷.

61 It is only appropriate then that when many cities in India are suffering through the second wave of the COVID-19 pandemic, many have turned to the internet, using applications/websites to find critical support. On these platforms, online communities led by members of the civil society and other individuals, have assisted the needy in multiple ways – often by helping them procure oxygen, essential drugs or find a hospital bed through their own networks or by amplifying original requests, and even by offering moral and emotional support. However, it is with deep distress that we note that individuals seeking help on such platforms have been targeted, by alleging that the information posted by them is false and has only been posted in social media to create panic, defame the administration or damage the “national image”. We do not hesitate in saying that such targeting

³⁵ “WHO”

³⁶ “Managing the COVID-19 infodemic: Promoting healthy behaviours and mitigating the harm from misinformation and disinformation - Joint statement by WHO, UN, UNICEF, UNDP, UNESCO, UNAIDS, ITU, UN Global Pulse, and IFRC” (WHO, 23 September 2020) available at <<https://www.who.int/news-room/detail/managing-the-covid-19-infodemic-promoting-healthy-behaviours-and-mitigating-the-harm-from-misinformation-and-disinformation>>

³⁷ “Social media & COVID-19: A global study of digital crisis interaction among Gen Z and Millennials” (WHO, 23 September 2020) available at <<https://www.who.int/news-room/feature-stories/detail/social-media-covid-19-a-global-study-of-digital-crisis-interaction-among-gen-z-and-millennials>>

shall not be condoned, and the Central Government and State Governments should ensure that they immediately cease any direct or indirect threats of prosecution and arrest to citizens who air grievances or those that are attempting to help fellow citizens receive medical aid. If this does keep happening even after the current order, this Court shall be constrained to use the powers available to it under its contempt jurisdiction. We also direct that all Directors General of Police shall ensure compliance down the ranks of the police forces within their jurisdictions.

62 In these trying times, those desperately seeking help for their loved ones on these platforms should not have their misery compounded through the actions of the State and its instrumentalities. Further, there are two more crucial reasons why such a clampdown on information sharing must be absolutely stopped immediately.

63 The first reason is because sharing information widely is in itself an important tool in combating public tragedies, like the current COVID-19 pandemic. In **K.S. Puttaswamy (Privacy-9J.) vs Union of India**³⁸, one of us (DY Chandrachud, J) speaking for four Judges of a nine-Judge bench of this Court noted academic literature documenting the widespread availability of information and the resultant acknowledgement of the problem is what prevented the drought in Maharashtra in 1973 from becoming as bad as the Bengal Famine of 1943, where the British tried to deny the problem even existed. It was noted thus:

“267. Civil and political rights and socio-economic rights do not exist in a state of antagonism. The conditions necessary for realising or fulfilling socio-economic rights do not postulate

³⁸ (2017) 10 SCC 1

the subversion of political freedom. The reason for this is simple. Socio-economic entitlements must yield true benefits to those for whom they are intended. This can be achieved by eliminating rent-seeking behaviour and by preventing the capture of social welfare benefits by persons who are not entitled to them. Capture of social welfare benefits can be obviated only when political systems are transparent and when there is a free flow of information. Opacity enures to the benefit of those who monopolise scarce economic resources.

On the other hand, conditions where civil and political freedoms flourish ensure that governmental policies are subjected to critique and assessment. It is this scrutiny which subserves the purpose of ensuring that socio-economic benefits actually permeate to the underprivileged for whom they are meant. Conditions of freedom and a vibrant assertion of civil and political rights promote a constant review of the justness of socio-economic programmes and of their effectiveness in addressing deprivation and want. Scrutiny of public affairs is founded upon the existence of freedom. Hence civil and political rights and socio-economic rights are complementary and not mutually exclusive.

268. Some of these themes have been addressed in the writings of the Nobel laureate, Amartya Sen. Sen compares the response of many non-democratic regimes in critical situations such as famine with the responses of democratic societies in similar situations. [Amartya Sen, *Development as Freedom* (Oxford University Press, 2000) at pp. 178-79.]...

269. In the Indian context, Sen points out that the Bengal famine of 1943 "was made viable not only by the lack of democracy in colonial India but also by severe restrictions on reporting and criticism imposed on the Indian press, and the voluntary practice of "silence" on the famine that the British-owned media chose to follow" [Amartya Sen, *The Idea of Justice* (Penguin Books, 2009) at p. 339.] . Political liberties and democratic rights are hence regarded as "constituent components" of development. [Id, at p. 347] In contrast during the drought which took place in Maharashtra in 1973, food production failed drastically and the per capita food output was half of that in sub-Saharan Africa. Yet there was no famine in Maharashtra where five million people were employed in rapidly organised public projects while there were substantial famines in sub-Saharan Africa. This establishes what he terms as "the protective role of democracy". Sen has analysed the issue succinctly:

"The causal connection between democracy and the non-occurrence of famines is not hard to seek. Famines kill millions of people in different countries in the world, but they

don't kill the rulers. The kings and the presidents, the bureaucrats and the bosses, the military leaders and the commanders never are famine victims. And if there are no elections, no opposition parties, no scope for uncensored public criticism, then those in authority don't have to suffer the political consequences of their failure to prevent famines. Democracy, on the other hand, would spread the penalty of famines to the ruling groups and political leaders as well. This gives them the political incentive to try to prevent any threatening famine, and since famines are in fact easy to prevent (the economic argument clicks into the political one at this stage), the approaching famines are firmly prevented." [Amartya Sen, *Development as Freedom* (Oxford University Press, 2000) at p. 180.]..."

(emphasis supplied)

As such, preventing clampdowns on sharing of information on online platforms is not just in the interest of individuals sharing the information, but the larger democratic structures of our nation. Without the ready availability of such information, it is entirely possible that the COVID-19 pandemic may turn into a tragedy worse than what it already is.

64 The second reason is because sharing information widely will help in the creation of a "collective public memory" of this pandemic. The presence of collective public memory, which refers "*to an extant and taken-for-granted group memory*"³⁹, is important for the creation of knowledge of the problems plaguing us today, so they may be passed on across time⁴⁰. This is important since we do not have to travel back too much in our past to realise that the pandemic caused by the "Spanish" flu of 1918, which is said to have infected every third person in the world and killed between 50-100 million individuals (compared to the 17 million

³⁹ Theodore O. Prosise, 'The collective memory of the atomic bombings misrecognized as objective history: The case of the public opposition to the national air and space museum's atom bomb exhibit', (1998) 62 Western Journal of Communication 3:316-347, pg 318

⁴⁰ Bryan Hubbard and Marouf A. Hasian, 'Atomic Memories of the 'Enola Gay': Strategies of Remembrance at the National Air and Space Museum' (1998) 1 Rhetoric and Public Affairs 3:363-385, pg 364

who died in World War I), has been almost entirely erased from our collective public memory⁴¹. Therefore, the widespread sharing of information by individuals living through the COVID-19 pandemic becomes crucial. Furthermore, the role of Courts in creating and preserving this collective public memory cannot be understated. Professors Austin Sarat and Thomas R. Kearns, in their book *History, Memory, and the Law*, describe the function that is played by Courts in the following terms⁴²:

"Law in the modern era is, we believe, one of the most important of our society's technologies for preserving memory. Just as the use of precedent to legitimate legal decisions fixes law in a particular relation to the past, memory may be attached, or attach itself, to law and be preserved in and through law. Where this is the case, it serves as one way of orienting ourselves to the future. **As Drucilla Cornell puts it:** "Legal interpretation demands that we remember the future." In that phrase, Cornell reminds us that there are, in fact, two audiences for every legal act, the audience of the present and the audience of the future. Law materializes memory in documents, transcripts, written opinions; it re-enacts the past, both intentionally and unconsciously, and it is one place where the present speaks to the future through acts of commemoration.

Because the litigated case creates a record, courts can become archives in which that record serves as the materialization of memory. Due process guarantees an opportunity to be heard by, and an opportunity to speak to, the future. It is the guarantee that legal institutions can be turned into museums of unnecessary, unjust, undeserved pain and death. The legal hearing provides lawyers and litigants an opportunity to write and record history by creating narratives of present injustices, and to insist on memory in the face of denial. By recording such history and constructing such narratives lawyers and litigants call on an imagined future to choose Justice over the "jurispathic" tendencies of the moment."

(emphasis supplied)

⁴¹ Jonathan Freedland, 'History suggests we may forget the pandemic sooner than we think' (*The Guardian*, 29 January 2021) available at <<https://www.theguardian.com/commentisfree/2021/jan/29/history-forget-pandemic-spanish-flu-covid>>

⁴² Austin Sarat and Thomas R. Kearns, *History, Memory, and the Law* (University of Michigan Press, 2009) pgs 12-13

Hence, in the present proceedings, we hope to not only initiate a dialogue so as to better tackle the current COVID-19 pandemic but also to preserve its memory in our public records, so that future generations may evaluate our efforts and learn from them.

65 We speak not only as members of this Court, but also as grateful citizens of the country, and commend the outstanding work of our all healthcare professionals (doctors, nurses, healthcare workers, laboratory technicians, ward staff, ambulance drivers, crematorium workers etc.) during this crisis. They have truly gone beyond their call of duty and toiled day in and day out, relentlessly without rest amidst great challenges. It is absolutely necessary to take urgent steps for their well-being to ensure that our appreciation for their tremendous efforts is not reduced to rhetoric. This is especially important since another factor which affects how collective public memory of any event is created is by the rhetoric surrounding it⁴³. As such, our public memory of this public event has to transcend its conception as a “war” against the virus of COVID-19 itself, but rather to remember that it is “*the complex epidemiological circumstances that promote these outbreaks and the under-resourced health systems that are tasked with disease containment*”⁴⁴. While the healthcare professionals have been at the forefront of tackling this crisis, we have to recognize their contribution as medical healthcare professionals who have undertaken “*to protect public health using*

⁴³ Nicole Maurantonio, "The Politics of Memory" in Kate Kenski and Kathleen Hall Jamieson (eds), *The Oxford Handbook of Political Communication* (Oxford University Press, 2014)

⁴⁴ Luke Shors, 'Waging Another Public Health "War?"' (*Think Global Health*, 26 February 2020) available at <<https://www.thinkglobalhealth.org/article/waging-another-public-health-war>>

*proven scientific evidence and best practices and to serve to community at large*⁴⁵, and not just as “CORONA WARRIORS”.

66 We also do not hesitate to note that the treatment meted out to these public healthcare professional during this COVID-19 pandemic has sometimes been less than ideal. The following are some of the issues we wish to highlight:

- (i) Recently, there were reports that the Pradhan Mantri Garib Kalyan Package Insurance Scheme, an insurance scheme of Rs 50 lakhs which had been extended to about 22 lakh healthcare professionals, was set to expire on 24 March 2021 and would not be renewed. While we are happy to note that UOI’s affidavit of 23 April 2021 states that this Scheme has been extended for one year starting April 2021, we have also been informed that till date only 287 claims have been settled under it, which includes claims from the families of 168 doctors who died after contracting COVID-19 while treating patients. We direct the Central Government to inform this Court as to how many claims are pending under the Scheme, and the timeline within which the Central Government expects to settle them;
- (ii) Healthcare personnel are at an obvious heightened risk of contracting the COVID-19 virus. However, we are aware of reports that indicate that infected healthcare personnel are left to fend for themselves without adequate availability of beds, oxygen or essential drugs. Further, some of them have also often been asked to report back to duty within 10 days of first testing positive for COVID-19 (provided they are asymptomatic), even

⁴⁵ Elena N. Naumova, ‘The traps of calling the public health response to COVID-19 “an unexpected war against an invisible enemy” (2020) Journal of Public Health Policy 41:233-237, pg 233

though a longer recuperation period is often recommended. While we are dealing with a terrible second wave of the COVID-19 pandemic, there must be an effective policy to ensure that the nation truly acknowledges their effort and creates incentives for them. We hope it will be remedied soon by the Central and State Governments through the introduction of appropriate guidelines and measures;

- (iii) It is unclear what measures are currently being taken to ensure that healthcare personnel can continue to serve others while not risking the health of their family members. We hope that the respective State Governments, with necessary assistance from the Central Government, can ensure this takes place; and
- (iv) The Central Government should, we feel examine and ensure that in addition to the schemes it has framed, other facilities such as availability of food, resting facilities during intervals between work, transportation facilities, non-deduction of salary or leave account, if afflicted by COVID 2019 or related infection, overtime allowance, in both public and private hospitals, and a separate helpline for doctors, and healthcare professionals, in cases of COVID 2019 related emergencies, is provided. All these, we feel, would show these professionals that we do not show our appreciation in mere words, but also care for them.

67 The issues mentioned above are only symptomatic of the other broader issues that are being faced by healthcare professionals, who are instrumental in combating the pandemic. Hence, we hope their welfare is considered seriously by the Central and State Governments. Further, we would wish to use this order to

place on record our sincerest appreciation for all the public healthcare professionals - not just limited to the doctors, but also nurses, hospital staff, ambulance drivers, sanitation workers and crematorium workers. It is through their dedicated efforts that the effect of COVID-19 pandemic is being currently tackled in India.

68 In light of the continuing surge of infections in the second wave of the pandemic, we direct the Central Government and State Governments to put on record the efforts taken to curb the spread of the virus and the measures that they plan on taking in the near future. At the same time, we would seriously urge the Central and State Governments to consider imposing a ban on mass gatherings and super spreader events. They may also consider imposing a lockdown to curb the virus in the second wave in the interest of public welfare. Having said that, we are cognizant of the socio-economic impact of a lockdown, specifically, on the marginalized communities. Thus, in case the measure of a lockdown is imposed, arrangements must be made beforehand to cater to the needs of these communities.

J Conclusion

69 The present order has primarily considered the submissions (written and oral) of the UOI. These submissions have been reproduced here as a matter of public record and to contextualize the clarifications that are being sought by our Court in order to serve its dialogic role. We reiterate, for abundant caution, that the data and submissions reproduced above are not its endorsement or acceptance. In terms of the above discussion, we hereby pass the following directions:

- (i) The UOI shall ensure, in terms of the assurance of the Solicitor General, that the deficit in the supply of oxygen to the GNCTD is rectified within 2 days from the date of the hearing, that is, on or before the midnight of 3 May 2021;
- (ii) The Central Government shall, in collaboration with the States, prepare a buffer stock of oxygen for emergency purposes and decentralize the location of the emergency stocks. The emergency stocks shall be created within the next four days and is to be replenished on a day to day basis, in addition to the existing allocation of oxygen supply to the States;
- (iii) The Central Government and State Governments shall notify all Chief Secretaries/Directors General of Police/Commissioners of Police that any clampdown on information on social media or harassment caused to individuals seeking/delivering help on any platform will attract a coercive exercise of jurisdiction by this Court. The Registrar (Judicial) is also directed to place a copy of this order before all District Magistrates in the country;
- (iv) The Central Government shall, within two weeks, formulate a national policy on admissions to hospitals which shall be followed by all State Governments. Till the formulation of such a policy by the Central Government, no patient shall be denied hospitalization or essential drugs in any State/UT for lack of local residential proof of that State/UT or even in the absence of identity proof;
- (v) The Central Government shall revisit its initiatives and protocols, including on the availability of oxygen, availability and pricing of vaccines, availability

of essential drugs at affordable prices and respond on all the other issues highlighted in this order before the next date of the hearing, that is, 10 May 2021. Copies of all affidavits to be served upon the *Amici* in advance; and

(vi) Several other suggestions have been made before this Court in IAs and writ petitions filed by diverse parties. In order to streamline the further course of hearing, we have requested the *Amici* to collate and compile these suggestions which would be taken up later. The present order has focused on certain critical issues in view of the urgency of the situation.

.....J.
[Dr Dhananjaya Y Chandrachud]

.....J.
[L Nageswara Rao]

.....J.
[S Ravindra Bhat]

New Delhi;
April 30, 2021

Nirman Bhawan, New Delhi
Dated the 8th May 2021

ORDER

Subject: National Policy for Admission in Hospitals

Ministry of Health and Family Welfare enunciated a policy of setting up three tier Health infrastructure for appropriate management of suspect/confirmed COVID-19 cases. The guidance document issued in this regard on 7th April 2020, envisages setting up of :

- a. COVID Care Center (CCC) that shall offer care for mild cases. These have been set up in hostels, hotels, schools, stadiums, lodges etc., both public and private. Functional hospitals like CHCs, etc, which may be handling regular, non-COVID cases may also be designated as COVID Care Centres as a last resort.
 - b. Dedicated COVID Health Centre (DCHC) that shall offer care for all cases that have been clinically assigned as moderate. These should either be a full hospital or a separate block in a hospital with preferably separate entry/exit/zoning. Private hospitals may also be designated as COVID Dedicated Health Centres. These hospitals would have beds with assured Oxygen support.
 - c. Dedicated COVID Hospital (DCH) that shall offer comprehensive care primarily for those who have been clinically assigned as severe. These Hospitals should either be a full hospital or a separate block in a hospital with preferably separate entry/exit. Private hospitals may also be designated as COVID Dedicated Hospitals. These hospitals would have fully equipped ICUs, Ventilators and beds with assured Oxygen support.
2. The above mentioned COVID health infrastructure has been aligned with clinical management protocol for admission of Mild cases to CCC, Moderate cases to DCHC and severe cases to DCH.
3. Further Pursuant to the order of the Hon'ble Supreme Court in Suo-Moto writ petition (Civil) No3 of 2021 dated 30th April 2021 and in exercise of powers delegated under the section 10(2) of the Disaster Management Act 2005 vide Order No. 40-2/2020 DM-1A Dated 11th March 2020, it is hereby directed that the Hospitals under the Central government, State Governments and Union territory administration including private hospitals (in States and Union Territories) managing COVID patients shall ensure the following:
- a) Requirement of a positive test for COVID-19 virus is not mandatory for admission to a COVID health facility. A suspect case shall be admitted to the suspect ward of CCC, DCHC or DHC as the case may be.
 - b) No Patient will be refused services on any count. This includes medications such as oxygen or essential drugs even if the patient belongs to a different city.
 - c) No patient shall be refused admission on the ground that he / she is not able to produce a valid identity card that does not belong to the city where the hospital is located.

: 2 :

- d) Admissions to hospital must be based on need. It should be ensured that beds are not occupied by persons who do not need hospitalization. Further, the discharge should be strictly in accordance with the revised discharge policy available at <https://www.mohfw.gov.in/pdf/ReviseddischargePolicyforCOVID19.pdf>
4. The Chief Secretaries of States/Union territories shall issue necessary orders and circulars, incorporating the above directions within three days, which shall be enforced till replaced by an appropriate uniform policy.



(Rajesh Bhushan)
Secretary

To

- i) Chief Secretaries of all States/UTs
- ii) Director, All AIIMS
- iii) Director/MS of all Central Government Hospitals

Copy to:

- i) Solicitor General of India
- ii) Registrar, Supreme Court
- iii) Additional Chief Secretary, Principal Secretary, Secretary (Health)
All States / UTs

Copy to

Cabinet Secretary, Cabinet Secretariat, Rashtrapati Bhawan, New Delhi

Annexure R/2

Ministry of Health & Family Welfare
Directorate General of Health Services
EMR Division

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Guidance document on appropriate management of suspect/confirmed cases of COVID-19

1. Introduction: Since its first detection in China, Coronavirus Disease 2019 (COVID-19) has now spread to over 210 countries/territories, with reports of local transmission happening across the world. As per WHO (as of 7th April, 2020), there has been a total of 12,14,466 confirmed cases and 67,767 deaths due to COVID-19 worldwide.

In India, as on 7th April, 2020, 4421 confirmed cases and 114 deaths reported from 31 States/UTs.

2. Purpose of this document

A series of measures have been taken by both the Central and State Governments to break the chain of transmission. One among these is to isolate all suspect and confirmed cases of COVID-19. However, as the number of cases increases, it would be important to appropriately prepare the health systems and use the existing resources judiciously. Available data in India suggests that nearly 70% of cases affected with COVID-19 either exhibit mild or very mild symptoms. Such cases may not require admission to COVID-19 blocks/ dedicated COVID-19 hospitals.

It is important to put in place mechanisms for triaging and decisions making for identification of the appropriate COVID dedicated facility for providing care to COVID-19 patients. The purpose of this document is to put in place such SOPs to ensure optimal utilization of available resources and thereby providing appropriate care to all the COVID-19 patients. This will ensure that available hospital beds capacity is used only for moderate to severe cases of COVID-19. The SOPs specified hereafter also specify the different types of facilities to be set up for various categories of Covid-19 cases.

Guiding principles

All the selected facilities must be dedicated for COVID management. Three types of COVID dedicated facilities are proposed in this document. All 3 types of COVID Dedicated facilities will have separate ear marked areas for suspect and confirmed cases. Suspect and confirmed cases should not be allowed to mix under any circumstances.

All suspect cases (irrespective of severity of their disease) will be tested for COVID-19. Further management of these cases will depend on their (i) clinical status and (ii) result of COVID-19 testing.

All three types of facilities will be linked to the Surveillance team (IDSP)

All these facilities will follow strict infection prevention and control practices

3. Types of COVID Dedicated Facilities: There are three types of COVID Dedicated Facilities –

(1) COVID Care Center (CCC):

- 1.1. The COVID Care Centers shall offer care only for cases that have been clinically assigned as **mild or very mild cases or COVID suspect cases**.
- 1.2. The COVID Care Centers are makeshift facilities. These may be set up in hostels, hotels, schools, stadiums, lodges etc., both public and private. If need be, existing quarantine facilities could also be converted into COVID Care Centers. Functional hospitals like CHCs, etc, which may be handling regular, non-COVID cases should be designated as COVID Care Centers as a last resort. This is important as essential non COVID Medical services like those for pregnant women, newborns etc, are to be maintained.
- 1.3. Wherever a COVID Care Center is designated for admitting both the confirmed and the suspected cases, these facilities **must have separate areas for suspected and confirmed cases with preferably separate entry and exit. Suspect and confirmed cases must not be allowed to mix under any circumstances.**
- 1.4. As far as possible, wherever suspect cases are admitted in the COVID Care Center, preferably individual rooms should be assigned for such cases.
- 1.5. Every Dedicated COVID Care Centre must necessarily be mapped to one or more Dedicated COVID Health Centres and at least one Dedicated COVID Hospital for referral purpose (details

given below).

- 1.6. Every Dedicated COVID Care Centre must also have a dedicated Basic Life Support Ambulance (BLSA) equipped with sufficient oxygen support on 24x7 basis, for ensuring safe transport of a case to Dedicated higher facilities if the symptoms progress from mild to moderate or severe.
- 1.7. The human resource to man these Care Centre facilities may also be drawn from AYUSH doctors. Training protocols developed by AIIMS is uploaded on MoHFW website. Ministry of AYUSH has also carried out training sessions. The State AYUSH Secretary/ Director should be involved in this deployment. State wise details of trained AYUSH doctors has been shared with the States. Their work can be guided by an Allopathic doctor.

(2) Dedicated COVID Health Centre (DCHC):

- 2.1. The Dedicated COVID Health Centre are hospitals that shall offer care for all cases that have been **clinically assigned as moderate**.
- 2.2. These should either be a full hospital or a separate block in a hospital with preferably separate entry\exit/zoning.
- 2.3. Private hospitals may also be designated as COVID Dedicated Health Centres.
- 2.4. Wherever a Dedicated COVID Health Center is designated for admitting both the confirmed and the suspect cases with moderate symptoms, these hospitals **must have separate areas for suspect and confirmed cases. Suspect and confirmed cases must not be allowed to mix under any circumstances**.
- 2.5. These hospitals would have beds with assured Oxygen support.
- 2.6. Every Dedicated COVID Health Centre must necessarily be mapped to one or more Dedicated COVID Hospitals.
- 2.7. Every DCHC must also have a dedicated Basic Life Support Ambulance (BLSA) equipped with sufficient oxygen support for ensuring safe transport of a case to a Dedicated COVID Hospital if the symptoms progress from moderate to severe.

(3) Dedicated COVID Hospital (DCH):

- 3.1. The Dedicated COVID Hospitals are hospitals that shall offer comprehensive care primarily for those who have been **clinically assigned as severe**.
- 3.2. The Dedicated COVID Hospitals should either be a full hospital or a separate block in a hospital with preferably separate entry\exit.

- 3.3. Private hospitals may also be designated as COVID Dedicated Hospitals.
- 3.4. These hospitals would have fully equipped ICUs, Ventilators and beds with assured Oxygen support.
- 3.5. These hospitals **will have separate areas for suspect and confirmed cases. Suspect and confirmed cases should not be allowed to mix under any circumstances.**
- 3.6. The Dedicated COVID Hospitals would also be referral centers for the Dedicated COVID Health Centers and the COVID Care Centers.

All these facilities will follow strict infection prevention and control practices.

4. Management of COVID cases

4.1. Assessment of patients:

In addition to patients arriving directly through helpline/ referral to above categories of COVID dedicated facilities, in field settings during containment operations, the supervisory medical officer to assess for severity of the case detected and refer to appropriate facility.

States\UTs may identify hospitals with dedicated and separate space and set up Fever Clinics in such hospitals. The Fever Clinics may also be set up in CHCs, in rural areas subject to availability of sufficient space to minimize the risk of cross infections. In urban areas, the civil\general hospitals, Urban CHCs and Municipal Hospitals may also be designated as Fever Clinics. These could be set up preferably near the main entrance for triage and referral to appropriate COVID Dedicated Facility. Wherever space allows, a temporary make shift arrangement outside the facility may be arranged for this triaging.

The medical officer at the fever clinics could identify suspect cases and refer to COVID Care Centre, Dedicated COVID Health Centre or Dedicated COVID Hospital, depending on the clinical severity.

4.2 Categorization of patients

Patients may be categorized into three groups and managed in the respective COVID hospitals – Dedicated COVID Care Centre, dedicated COVID Health Centre and dedicated COVID

Hospitals.

Group 1: Suspect and confirmed cases clinically assigned as mild and very mild

Group 2: Suspect and confirmed cases clinically assigned as moderate

Group 3: Suspect and confirmed cases clinically assigned as severe

Group 1: Suspect and confirmed cases clinically assigned as mild and very mild (COVID Care Centres)

- **Clinical criteria:** Cases presenting with fever and/or upper respiratory tract illness (Influenza Like Illness, ILI).
- These patients will be accommodated in COVID Care Centers.
- The patients would be tested for COVID-19 and till such time their results are available they will remain in the “suspect cases” section of the COVID Care Center preferably in an individual room.
- Those who test positive, will be moved into the “confirmed cases” section of the COVID Care Center.
- If test results are negative, patient will be given symptomatic treatment and be discharged with advice to follow prescribed medications and preventive health measures as per prescribed protocols.
- If any patient admitted to the COVID Care Center qualifies the clinical criteria for moderate or severe case, such patient will be shifted to a Dedicated COVID Health Centre or a Dedicated COVID Hospital.
- Apart from medical care the other essential services like food, sanitation, counseling etc. at the COVID Care Centers will be provided by local administration. Guidelines for quarantine facilities (available on MoHFW website) may be used for this purpose.

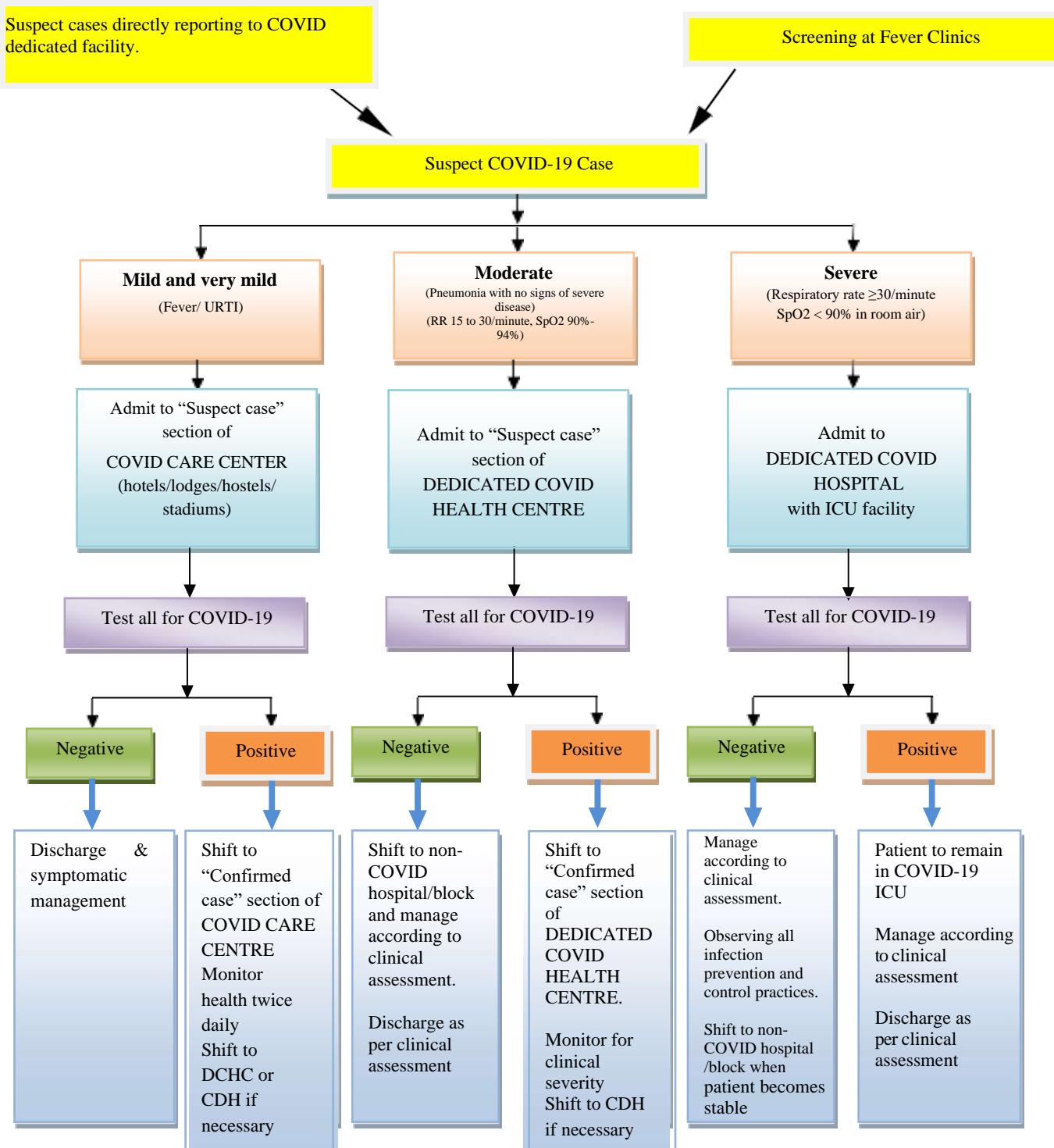
Group 2: Suspect and confirmed cases clinically assigned as moderate (Dedicated COVID Health Centres)

- **Clinical criteria:** Pneumonia with no signs of severe disease (Respiratory Rate ≥ 30 /minute, SpO₂ 90%-94%).
- Such cases will not be referred to COVID Care Centers but instead will be admitted to Dedicated COVID Health centres.
- It will be manned by allopathic doctors and cases will be monitored on above mentioned clinical parameters for assessing severity as per treatment protocol (available on MoHFW website).
- They will be kept in “suspect cases” section of Dedicated COVID Health Centres, till such time as their results are not available preferably in an individual room.
- Those testing positive shall be shifted to “confirmed cases” section of Dedicated COVID Health Centre.
- Any patient, for whom the test results are negative, will be shifted to a non-COVID hospital and will be managed according to clinical assessment. Discharge as per clinical assessment.
- If any patient admitted to the Dedicated COVID Health Center qualifies the clinical criteria for severe case, such patient will be shifted to a Dedicated COVID Hospital.

Group 3: Suspect and confirmed cases clinically assigned as severe (Dedicated COVID Hospital)

- **Clinical criteria:** Severe Pneumonia (with respiratory rate ≥ 30 /minute and/or SpO₂ < 90% in room air) or ARDS or Septic shock
- Such cases will be directly admitted to a Dedicated COVID Hospital’s ICU till such time as test results are obtained.
- If test results are positive, such patient will remain in COVID-19 ICU and receive treatment as per standard treatment protocol. Patients testing negative will be managed with adequate infection prevention and control practices.

Algorithm for isolation of suspect/confirmed cases of COVID-19



Revised Discharge Policy for COVID-19

The revised discharge policy is aligned with the guidelines on the 3 tier COVID facilities and the categorization of the patients based on clinical severity (Available at:

<https://www.mohfw.gov.in/pdf/FinalGuidanceonMangaementofCovidcasesversion2.pdf>)

1. Mild/very mild/pre-symptomatic cases

Mild/very mild/pre-symptomatic cases admitted to a COVID Care Facility will undergo regular temperature and pulse oximetry monitoring. The patient can be discharged after 10 days of symptom onset and no fever for 3 days. There will be no need for testing prior to discharge.

At the time of discharge, the patient will be advised to isolate himself at home and self-monitor their health for further 7 days.

At any point of time, prior to discharge from CCC, if the oxygen saturation dips below 95%, patient is moved to Dedicated COVID Health Centre (DCHC).

After discharge from the facility, if he/she again develops symptoms of fever, cough or breathing difficulty he will contact the COVID Care Centre or State helpline or 1075. His/her health will again be followed up through tele-conference on 14th day.

2. Moderate cases admitted to Dedicated COVID Health Centre (Oxygen beds)**2.1. Patients whose symptoms resolve within 3 days and maintains saturation above 95% for the next 4 days**

Cases clinically classified as “moderate cases” will undergo monitoring of body temperature and oxygen saturation. If the fever resolve within 3 days and the patient maintains saturation above 95% for the next 4 days (without oxygen support), such patient will be discharged after 10 days of symptom onset in case of:

- Absence of fever without antipyretics
- Resolution of breathlessness
- No oxygen requirement

There will be no need for testing prior to discharge.

At the time of discharge, the patient will be advised to isolate himself at home and self-monitor their health for further 7 days.

2.2. Patient on Oxygenation whose fever does not resolve within 3 days and demand of oxygen therapy continues

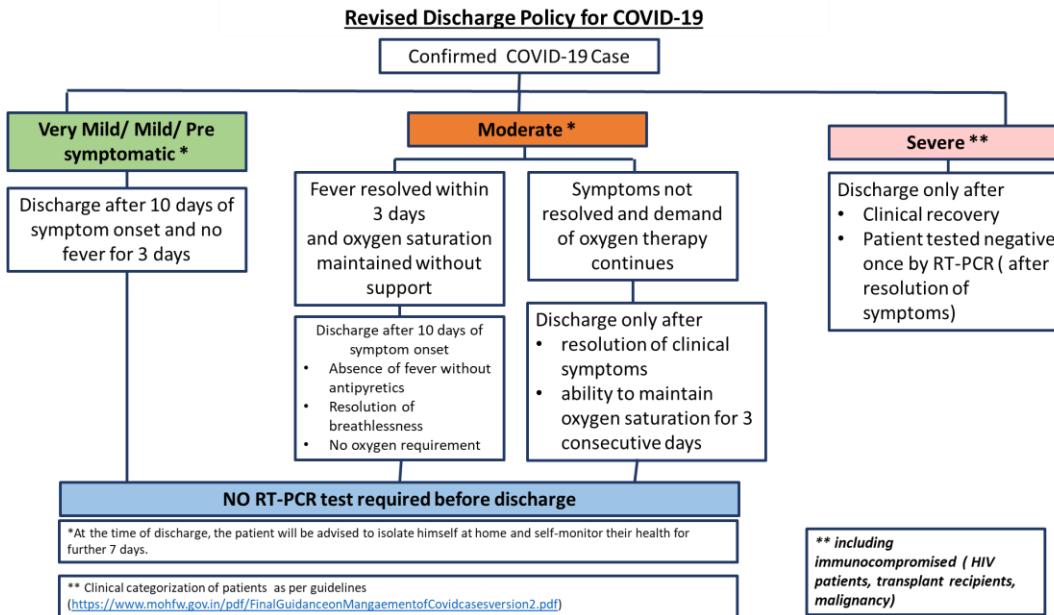
Such patients will be discharged only after

- resolution of clinical symptoms
- ability to maintain oxygen saturation for 3 consecutive days

3. Severe Cases including immunocompromised (HIV patients, transplant recipients, malignancy)

Discharge criteria for severe cases will be based on

- Clinical recovery
- Patient tested negative once by RT-PCR (after resolution of symptoms)



Annexure R/3

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No. Z. 20015/43/2021 – ME-I (FTS-8108321)

Government of India

Ministry of Health and Family Welfare

MEP Section

Nirman Bhawan, New Delhi

Dated the 3rd May 2021

To,

Additional Chief Secretary/Principal Secretary Health/Medical education
All States/UTs

Subject: Augmenting Human resources for COVID – 19 – regarding.

Madam/Sir,

In view of the need for increasing the availability of trained human resources to tackle the Covid-19 pandemic situation, the following Guidelines are being issued in consultation with the National Medical Commission and the Indian Nursing Council.

I -RELAXATION/FACILITATION/EXTENSION

1. Considering the current situation in the wake of resurgence of COVID – 19, National Eligibility cum Entrance Test-NEET (PG) – 2021 is being postponed. This Exam will not be held before 31st August 2021. At least one-month time will be given after the announcement of the Examination before it is conducted. The State/UT Governments are to make all efforts to reach out to each such prospective NEET candidate and persuade them to join the Covid – 19 workforce in this hour of need. The services of these MBBS doctors can be utilized in the management of COVID – 19.
2. The State/UT Governments may deploy Medical Interns in Covid Management duties under the supervision of their faculty, as part of the Internship rotation.
3. The services of Final Year MBBS students can be utilized for providing services like tele-consultation and monitoring of mild Covid cases after due orientation by and supervision of Faculty.
4. The services of Final Year PG Students (broad as well as super-specialities) as residents may continue to be utilized until fresh batches of PG Students have joined. Likewise, the services of the senior residents / registrars may continue to be utilized until new recruitments are made.
5. B.Sc./GNM Qualified Nurses may be utilized in full-time Covid nursing duties in ICU, etc., under the supervision of Senior Doctors and Nurses.
6. Final Year GNM or B.Sc. (Nursing) students awaiting Final Exam may be given full time Covid Nursing duties at Government/Private facilities under the supervision of Senior

Faculty.

7. The services of Allied Health Care professionals may be utilized for assistance in Covid Management, based on their training and certification.

8. The additional human resources thus mobilized should be used only in facilities managing Covid.

II – INCENTIVES/ RECOGNITION OF SERVICE

9. Health is a State subject and human resources for health are largely engaged by State Governments. The Central Government engages for their own institutions. The private sector also engages a large number of Health professionals.

10. The relaxation mentioned above, finalized in consultation with the National Medical Commission and the Indian Nursing Council, is to further augment human resources for responding to Covid-19 and should be fully availed by public and private institutions engaged in the effort.

11. The National Health Mission (NHM) norm for contractual human resource engagement by States/UTs may be considered for implementation of the above proposed initiative for engaging additional manpower. Flexibility will be available with States to decide on remuneration as in the NHM norms. A suitable honorarium for distinguished Covid Service may also be considered

12. The financial incentives/ remuneration shall be available only for those who work for at least 100 days for Covid care.

13. All Health professionals thus engaged will be covered under the Insurance Scheme of Government for health workers fighting Covid 19.

14. All such professionals who sign up for minimum 100 days of Covid duty and complete it successfully will be given the Prime Minister's Distinguished Covid National Service Samman from Government of India.

15. State/UT Governments can provide additional health professionals engaged through this process, to private Covid Hospitals as well in surge areas.

16. State Governments/ UT administrations are to ensure that the medical professionals sought to be engaged in Covid related work are suitably vaccinated.

17. The Central Government recommends to State/UT Governments to consider giving preference in regular Government appointments of Health professionals through the respective Public Service Commission/ other recruitment bodies, for those Health Professionals under this special scheme, who complete a minimum of 100 days of Covid related duty.

18. The State / UT Governments may also expeditiously fill vacant posts of doctors, nurses,

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allied healthcare professionals and other healthcare staff in Health and Medical departments through accelerated processes as soon as possible and positively within 45 days through contractual appointments.

2. This has the approval of competent authority.

Yours faithfully,

(Amit Biswas)
Under Secretary to the Government of India

Copy for necessary action to:

1. AS&MD, NHM, MoHFW.
2. The Secretary, National Medical Commission, Dwarka, New Delhi.
3. The Secretary, Indian Nursing Council, New Delhi.
4. The Executive Director, National Board Examination, New Delhi
5. CEO, Health, Niti Aayog.

Copy for information to.

1. The Director, PMO, New Delhi.
2. PS to Hon'ble HFM
3. PS to Hon'ble MOS(HFW)
4. PPS to Secretary (HFW)/PPS to AS(ME)/PPS to JS(ME)/DS(AHS/N)
5. PS to Member (Health), Niti Aayog.

Annexure R/4

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ITEM NO. 35

Court 5 (Video Conferencing)

SECTION XIV

S U P R E M E C O U R T O F I N D I A RECORD OF PROCEEDINGS

SPECIAL LEAVE PETITION (CIVIL) Diary No(s) .11622/2021

(Arising out of impugned final judgment and order dated 01-05-2021 in WP(C) No. 3031/2020 and 04-05-2021 in WP(C) No. 3031/2020 passed by the High Court of Delhi at New Delhi)

UNION OF INDIA

Petitioner(s)

VERSUS

RAKESH MALHOTRA & ANR.

Respondent(s)

Date : 06-05-2021 These petitions were called on for hearing today.

CORAM :

HON'BLE DR. JUSTICE D.Y. CHANDRACHUD
HON'BLE MR. JUSTICE M.R. SHAH

Mr. Jaideep Gupta, Sr. Adv. (A.C.)
Ms. Meenakshi Arora, Sr. Adv. (A.C.)
Mr. Mohit D Ram, AOR
Mr. Kunal Chatterji, AOR

For Petitioner(s) Mr. Tushar Mehta, SG
Ms. Aishwarya Bhati, ASG
Mr. Rajat Nair, Adv.
Mr. Kanu Agrawal, Adv.
Mr. Amit Mahajan, Adv.
Mr. Prashant Singh B, Adv.
Mr. Raj Bahadur Yadav, AOR
Mr. Gurmeet Singh Makkar, AOR
Mr. B. V. Balaram Das, AOR

For Respondent(s) Mr. Rahul Mehra, Sr. Adv.
Mr. Gautam Narayan, AOR
Mr. Satyakam, Adv.
Ms. Asmita Singh, Adv.
Mr. Adithya Nair, Adv.

Mr. Rakesh Malhotra, In Person
Mr. Tungesh, Adv.

UPON hearing the counsel the Court made the following

O R D E R

- 1 On 5 May 2021, three specific issues were flagged by this Court:
- (i) The methodology adopted by the Union Government for computing the requirement of oxygen of the States and Union Territories¹;
- (ii) The need to manage available resources of oxygen to optimise their availability for the National Capital Territory of Delhi², which is dependent on:
- An efficient supply chain;
 - Proper distribution of oxygen from the supply points to hospitals; and
 - Building buffer stocks of oxygen; and
- (iii) Actual availability of oxygen.

Though the proceedings on 5 May 2021 arose in the context of a notice issued by the High Court of Delhi in its contempt jurisdiction, many of the issues which have been recorded in the order are in continuation of the previous directions issued on 27 April 2021 and 30 April 2021 in **Re: Distribution Of Essential Supplies And Services During Pandemic**³. The issues faced by NCTD do in significant ways raise common areas of concern for the rest of the country.

¹ "UT"

² "NCTD"

³ Suo Motu Writ Petition (Civil) No 3 of 2021

2 To obviate burdening the text of this order with copious references to the previous directions, the effort of the Court would be to build upon the developments which have taken place since the exercise of the jurisdiction by the Court of its own accord at the inception of the proceedings. It will suffice to note that on 30 April 2021, some of the key issues pertaining to the supply of oxygen have been identified. These have been set out in the order and are extracted below:

“(i) Supply of oxygen – The Court should be apprised by the Union of India on

- (a) The projected demand for oxygen in the country at the present point of time and in the foreseeable future;
- (b) The steps taken and proposed to augment the availability of oxygen, meeting both the current and projected requirements;
- (c) The monitoring mechanism for ensuring the supply of oxygen, particularly to critically affected States and Union Territories as well as the other areas;
- (d) The basis on which allocation of oxygen is being made from the central pool; and
- (e) The methodology adopted for ensuring that the requirements of the States are communicated to the Central Government on a daily basis so as to ensure that the availability of oxygen is commensurate with the need of each State or, as the case may be, Union Territory.”

These excerpts indicate the broad areas of concern towards ensuring:

- (i) Determination of the quantum of oxygen required by each State and UT by the application of a rational and scientific methodology;
- (ii) Allocation of the resources of oxygen to States/UTs on the basis of such a methodology;

- (iii) Ensuring efficiency in the distribution of oxygen from the points of supply through distribution network which reach the ultimate users - institutional and individual, as the case may be;
- (iv) Monitoring the supply and distribution of oxygen;
- (v) Adopting steps for augmenting the available resources, on the basis of the present demand and projected increase of demand, based on the stage of the pandemic;
- (vi) Designing and monitoring an efficient system of transportation and other logistical arrangements which ensure seamless movement across the supply chain; and
- (vii) Creating buffer stocks capable of being accessible in the case of emergencies.

3 Apart from the issues of general concern and applicability which have been noted above, the specific issue pertaining to the allocation and distribution of oxygen to the NCTD has also seized the attention of this Court. In the order dated 30 April 2021, specific directions were issued in regard to the fulfilling its requirement for oxygen. The directions in paragraph 29 of the order are recapitulated below:

- (i) Though the projected daily demand of NCTD as of 20 April 2021 had increased from 300 MT to 700 MT, the existing allocation had remained at 490 MT per day;
- (ii) This situation must “be remedied forthwith”;

- (iii) On the intervention of the Court, the Union Government had stated that the demands for medical oxygen of NCTD would be met and that it would not suffer due to a lack of oxygen;
- (iv) A peremptory direction was issued by the Court in the above terms; and
- (v) The assurance of the Union Government that “henceforth” the deficit of oxygen would be rectified and supplies would be made to NCTD according to their projected demands (which could be revised in the future) on a day to day basis would be complied with by the midnight of 3 May 2021.

4 Following the above order, the High Court of Delhi issued a notice of contempt on 4 May 2021 for alleged non-compliance of its directions and those of this Court, with regard to the supply of 700 MT of oxygen to NCTD by the Union Government. These proceedings were then initiated to challenge the notice of contempt issued by the High Court. This Court, in its order dated 5 May 2021, stayed the invocation of the contempt jurisdiction, but directed that the directions contained in the order dated 30 April 2021 “must be duly implemented”. While staying the contempt proceedings, an opportunity was granted to the Union Government to place a plan indicating the manner in which the 700 MT daily requirement of NCTD would be fulfilled. The Court observed:

“...an opportunity should be granted to the Central Government to place before this Court a plan specifically indicating the manner in which the requirement of the NCT of Delhi of 700 MT in terms of the order of this Court dated 30 April 2021 will be complied with, pending further directions of this Court. In order to furnish an opportunity to the Central Government to place a tabulated statement before this Court, we adjourn the proceedings to 11.00 am tomorrow when this Bench will assemble for its regular assignment of work. We accordingly direct that by 11.00 am tomorrow, the Central Government shall place a comprehensive plan before this

Court indicating the manner in which the direction for the allocation of 700 MT of LMO to Delhi shall be complied with. The plan shall indicate:

- (i) Sources of supply;
- (ii) Provisions for transportation; and
- (iii) All other logistical arrangements necessary to ensure the fulfillment of the requirement of NCT of Delhi in terms of the order of this Court.”

5 In pursuance of the above directions, a proposal has been placed on the record by the Solicitor General. The Union Government has indicated that on 5 May 2021, 730.7 MT of oxygen has been received in the NCTD. The status of the availability of oxygen at hospitals and major re-filers as tabulated is extracted below:

“The availability of oxygen at major hospitals and re-filers

in Delhi: Status:

Hospitals (56)

Current stock: 280 MT

Average daily consumption: 290 MT

Storage capacity: 478 MT

Re-filers(11)

Current stock: 73 MT

Average daily consumption: 82 MT

Storage capacity: 187 MT

Total (Hospitals + Re-filers)

Current stock: 353 MT

Average daily consumption: 372 MT

Storage capacity: 665 MT”

6 The Union Government has submitted that:

- (i) There is a need to unload stocks expeditiously so as to obviate a delay in the turnaround of tankers;
- (ii) 280 MT of oxygen is arriving into NCTD by ‘oxygen express trains’.
- (iii) The requirement of NCTD, factually, is not 700 MT per day; and

- (iv) In order to ensure the delivery of the above quantity to NCTD, allotments to other States may have to be reduced.

Appended to the note submitted by the Solicitor General, is a plan detailing the transportation of 700 MT to NCTD. The plan, which is proposed for the transportation of 700 MT, indicates three sources of supply for ensuring the allocation to NCTD. These are:

"I. Synopsis

A. Existing Allocation and Supply (Already operationalised) -
490 MT (30 MT not being supplied by India Glycols)

B. Existing Allocation (Being Operationalised) - 100 MT + 40
MT (30 MT to compensate for India Glycols + 10 MT overall)

C. Special Allocation - 100 MT

$$\text{A+B+C} = 460 + 140 + 100 = 700 \text{ MT}$$

The special allocation of 100 MT is from RIL Jamnagar, Gujarat.

7 Having provided a plan for ensuring the supply of 700 MT to NCTD to meet the daily requirement in terms of the previous orders dated 30 April 2021 and 5 May 2021, there is a tabulated statement at the end of the plan which indicates the following position:

"Conclusion

Date of arrival of oxygen in Delhi	A (Existing Allocation already operationalised) (MT)	B (Existing allocation being operationalized) (MT)	C (Special Allocation) (MT)	Total (MT)	Remarks
06.05.2021	460*	-	100	560	*120 MT coming daily from Durgapur is contingent on LINDE getting 6 containers. As on date, capacity to only

					transfer 90 MT with 18 containers available with Linde
07.05.2021	460	-	100	560	
08.05.2021	460	-	100	560	
09.05.2021	460	80 (4 containers from IOCL)	100	640	4 ISO containers being made available by IOCL to transport 80 MT
10.05.2021	460	140 (7 containers from DP World)	100	700	
11.05.2021	460		100	560	
12.05.2021	460		100	560	
13.05.2021	460	80 (4 containers from IOCL)	100	640	4 ISO containers being made available by IOCL to transport 80 MT
14.05.2021	460	140 (7 containers from DP World)	100	700	

Even the above tabulation is contingent, as is indicated in the note and caveat appended to the plan, which are extracted below:

"Total requirement of containers for supplying 700 MT daily to Delhi is contingent upon:

- Making available 6 additional ISO containers for Durgapur
- Making available 24 additional ISO containers for Kalinganagar

Caveat:

1. ***The above plan for transportation of 700 MT to Delhi daily successfully is subject to availability of sufficient number of containers for deployment which are being***

procured on lease from abroad by various agencies like IOCL, Reliance and Linde.

2. Allocation of containers as per the plan might lead to an inadequate number of containers being made available for transportation of oxygen to other states."

(emphasis supplied)

8 The Solicitor General submits that:

- (i) The formula on the basis of which oxygen is being allocated to the States and UTs is not static but needs to be re-visited;
- (ii) There is an adequate quantity of oxygen-resources and steps for augmentation are being undertaken at the highest level;
- (iii) The existing quantity needs to be allocated to the States and UTs; and
- (iv) A continuous process of importing tankers for transportation is being conducted to resolve bottlenecks.

With the above premises, it has been submitted that:

- (i) Many of the demands by the States and UTs, including Government of NCT of Delhi⁴, for the provision of medical oxygen were ‘unrealistic’;
- (ii) As a result of these projections, it became necessary for the Union Government to make an assessment, for which a formula was devised;
- (iii) The problem of shortage in NCTD is due to a systemic failure to ensure proper distribution of oxygen;
- (iv) In order to resolve the issue, it would be necessary to conduct an audit in regard to the manner in which the available supplies are distributed through the networks and are ultimately utilised;

⁴ “GNCTD”

- (v) In order to facilitate a fresh assessment of the basis for allocation of oxygen, an expert committee may be constituted consisting of persons drawn from public and private healthcare institutions with experience in the field; and
- (vi) In order to ensure that the allocation and distribution of oxygen takes place on a rational and equitable basis, it is necessary to constitute a national task force of experts which would determine the method of allocation and distribution of oxygen across States/UTs. Smaller expert committees or sub-groups may look into issues of auditing the manner in which supplies are to be distributed and utilised in each State/UT.

9 While responding to the submissions of the Solicitor General, Mr Rahul Mehra, learned Senior Counsel appearing on behalf of the GNCTD, has welcomed the supply of 730.7 MT of oxygen under the auspices of the allocation made by the Union Government. At the same time, he has expressed the apprehension that as of 9 am on 6 May 2021, a total quantity of 189.532 MT has been delivered, and a quantity of 16.32 MT is in transit to the knowledge of GNCTD, resulting in a total availability of only 206 MT (approximately). As opposed to this, Mr Mehra stated that on the previous two days, an average of 300 MT had been received by NCTD by 9 am. Mr Mehra has highlighted during the course of his submissions that:

- (i) A team of officers is deployed by GNCTD to ensure that the distribution networks are monitored and the needs of healthcare institutions and refillers are met;

- (ii) The daily requirement of 700 MT for NCTD has been computed on the basis of the formula adopted by the Union Government, without factoring in an additional requirement of 256 MT consequent upon setting up of new facilities (including a facility being set up by DRDO);
- (iii) The additional facilities cannot be put to use for want of oxygen;
- (iv) The plan submitted by the Union Government is not in terms of the order of this Court dated 5 May 2021 but seeks, in substance, a review of the order dated 30 April 2021, which is impermissible as the present hearing was confined to a challenge to the Delhi High Court's exercise of its contempt jurisdiction;
- (v) No attention has been devoted by the Union Government to the need to create a buffer stock, as was directed by this Court in its order dated 30 April 2021;
- (vi) The additional requirement of NCTD (from 490 MT to 700 MT) is only 210 MT, which is a small fraction of the pan-India availability of oxygen, estimated at 8410 MT by the Union Government. Further, the actual oxygen lifted by the respective States/UTs (as on 28 April 2021), out of their allocated quantity, was only 7334.53 MT;
- (vii) No material has been produced to show that any other State would be affected by supplying the additional quantity to NCTD to make up the total requirement of 700 MT;
- (viii) The data placed on the record of the High Court by the Union Government indicates that the Union Government has made full allocations to certain States and excess to others, as against their projected demands. However,

the NCTD was only allocated with 490 MT, as against its demand of 700 MT as on 21 April 2021;

- (ix) There is no need for an audit and, if at all an audit is to be conducted, it should be of the availability of tankers;
- (x) In any event, the exercise of carrying an audit would be meaningless unless the formula pursuant to which the Union Government is allocating oxygen is revisited; and
- (xi) Several steps have been taken by GNCTD to bring about efficiencies in the transportation of oxygen; for instance, the tankers which have been recently acquired are being tracked on a real time basis through GPS.

10 Mr Jaideep Gupta and Ms Meenakshi Arora, learned Senior Counsel appearing as *amicus curiae*, emphasised certain crucial issues. *First*, both the Senior Counsel emphasised the necessity of factoring in the **projected demand for oxygen**, in realistically assessing the demand of oxygen in the foreseeable future. It would be necessary to associate with the work of the Task Force, epidemiologists, virologists and public health experts, who can draw upon their expertise for designing modelling-based estimates for the future. *Second*, contrary to the directions which were issued by this Court on 5 May 2021 that 700 MT of oxygen must be supplied to the NCTD, no concrete plan has been provided by the Union Government. *Third*, it is crucial for this Court to ensure that the daily requirement of NCTD of 700 MT is fulfilled by the Union Government. *Fourth*, there can be absolutely no dispute regarding the existence of oxygen shortages in the NCTD, warranting the need to maintain the existing requirement at 700 MT per day, besides building up buffer stocks.

11 These submissions can be analysed further in the context of the ground covered by the earlier orders.

12 The directions contained in the order of this Court dated 30 April 2021 leave no manner of doubt that the Union Government is under an obligation to ensure a daily supply of 700 MT to meet the existing requirements of the NCTD. This direction has been based on the assurance of the Union Government to the Court. The High Court of Delhi, finding that there was a breach of this direction, invoked the contempt jurisdiction. While the invocation of the coercive process has been stayed, this Court in its order dated 5 May 2021 has reiterated the direction for maintaining the supplies to NCTD at 700 MT per day. The Union Government was required to place on the record, a plan to achieve the fulfilment of this direction. The plan which has been placed before this Court is subject to caveats and conditions which cannot be accepted. What is sought to be assured in the first part of the plan is diluted with the next segment. 700 MT was not intended to be a requirement to be fulfilled for one day or sporadically, but on a daily basis. Daily basis means for every day. We accordingly direct, that there shall be no reduction in the allocation and availability of medical oxygen to NCTD and the direction in regard to the provision of 700 MT per day shall continue to be observed.

13 On 30 April 2021, the order of this Court recorded the submission of the Union Government that there is "**no dearth of oxygen**". The shortage of oxygen in the States/ UTs was attributed to deficiencies in distribution and the inability to

lift the entire quantity of oxygen supplied. For convenience of reference, the relevant part is extracted below:

"26 Based on the above facts and figures, the Solicitor General has stated that there is no dearth of oxygen supply in the country as on date and steps are being taken continuously to augment the supply of oxygen. Having said that, the Solicitor General has also admitted that there has been a shortage of supply to certain States and has attributed this **shortage to various factors including the failure of State Governments to lift the allocated quantity of oxygen from the supply point; transportation bottlenecks caused by inter-State movement of tankers; and technical failure of certain plants leading to reassessment of allocation on a real time basis."**

(emphasis supplied)

14 The Union Government has also on record stated that, as on 21 April 2021, a quantity of 16,000 MT of LMO is available in the country. The relevant extract is reproduced below for convenience of reference:

"These actions have already been taken by the steel manufacturers both in private and public sector which has resulted in immediate enhancement of LMO production/capacity by 293 MT. Apart from the current generation of LMO, the steel sector has made available the liquid oxygen available in its storage tanks for medical use (approximately 16,000 MT LMO is available as on 21st April 2021). Further, the safety stocks in the storage tanks of liquid oxygen at all locations has been brought down to 0.5 days in order to make available additional LMO. Till date the steel industry has supplied 143,000 MT of LMO since September 2020. As such, in the month of April 2021, supplies of LMO by the steel sector have increased from 1000 MT per day in the first week of April 2021 to around 2600 MT on 21st April 2021."

(emphasis supplied)

15 Except for a bare assertion that an increase of 210 MT to NCTD would result in a corresponding reduction to other States, no material has been produced on the record by the Union of India. On the contrary, the data produced before this court in regard to the allocation and supply of oxygen to NCTD indicates the following position:

Details of Oxygen Received in Delhi at 09 AM FROM 28.04.2021 to 06.05.2021												
NAME OF MANUFACTURER	LOCATION	ALLOCATED	28.04.2021	29.04.2021	30.04.2021	01.05.2021	02.05.2021	03.05.2021	04.05.2021	05.05.2021	06.05.2021	
			RECEIVED	RECEIVED	RECEIVED	RECEIVED	RECEIVED	RECEIVED	RECEIVED	RECEIVED	RECEIVED	
AIR LIQUID	PANIPAT	170	74.61	63.78	37.05	64.04	47.94	39.69	66.77	15.44	24.95	
	ROORKEE	20	0	0	0	0	20	12	0	0	0	
LINDE	JAMSHEDPUR-30	255	0	0	14.06	20.99	33.74	23.55	150.76	23.54	42.86	
	ROURKELA-40											
	SELAQUI (FARIDABAD)											
	DURGAPUR-30											
INOX	SURAJPUR	35	10.7	9.69	4.72	10.06	6.04	4.39	9.96	11.46	4.42	
	MODI NAGAR	30	3.23	29.52	17.61	25.38	0	0	0	7.25	15.3	
	BARTIWALA	20	0	0	0	0.99	0	0	0	0	0	
GOYAL GLASSES	GHAZIABAD	30	17.9	0	0	0	0	0	0	0	0	
INDIA GLYCOLS	KASHIPUR	30	0	0	0	0	0	0	0	0	0	
JINDAL STEEL POWER	RAIPUR		0	0	0	0	0	0	0	0	0	
ADDITIONAL SUPPLY OF 103MT FROM RELIANCE, JAMNAGAR			0	0	0	0	0	0	80	103	102	
ADDITIONAL SUPPLY OF 140 MT FROM M/S DP World, Mundra			0	0	0	0	0	0	0	140	0	
SETH TRADERS THROUGH LINDE	FARIDABAD		0	0	0	0	0	0	0	0	0	
	TOTAL	590	106.44	102.99	73.44	121.46	107.72	79.63	307.49	300.69	189.53	

PRIOR ALLOCATION TO DELHI AS ON 01.05.2021 WAS 490 MT

16 GNCTD has stated that it has computed the requirement of oxygen on the basis of the formula which has been adopted by the Union Government. The Union Government has not disputed the correctness of the computation on the basis of the formula. At this stage, no contrary material has been placed on the record by the Union Government. The attention of the Court has not been drawn to any error in the methodology of computation which has been adopted by GNCTD. GNCTD has drawn the attention of the Court to the serious deficiency in the availability of oxygen. This indicates that on 6 May 2021, the total quantity of oxygen delivered to NCTD was 577 MT, resulting in a shortfall of 123 MT. As of 9

am on 7 May 2021, the total quantity which has been received at NCTD border is 87.97 MT, while 9.64 MT is under transit. We direct the Union of India to remedy the situation forthwith and to ensure that the direction issued by this Court for the availability of 700 MT is strictly observed on a daily basis, pending further orders.

National Task Force

17 During the course of the hearing, a consensus has emerged that there is a need to ensure that the allotments of medical oxygen to the States and UTs is made on a scientific, rational and equitable basis. At the same time, it must allow for flexibility to meet unforeseen demands due to emergencies which may arise within the allocated territories. The formula which has been adopted by the Union Government has been adverted to in the earlier order dated 5 May 2021. Some of the deficiencies in regard to the basis and methodology have been flagged earlier. The Court suggested that an expert body drawn of *inter alia* renowned national experts with diverse experience in health institutions can be considered for being set up as a National Task Force, which will provide a public health response to the pandemic on the basis of a scientific approach. The Solicitor General informed the Court that the Union Government has responded favourably to the suggestion and in fact, his submissions, which have been adverted to earlier, record this specifically. It is necessary that an effective and transparent mechanism is set up within the Union Government for the purpose of allocating medical oxygen to all States and UTs for being used during the COVID-19 pandemic. The Union Government has agreed to set up a National

Task Force⁵ to streamline the process. This Task Force would be tasked *inter alia* with formulating a methodology for the scientific allocation of oxygen to the States and UTs. The Union Government has made its suggestions on the possible names for inclusion in the composition of the Task Force, while leaving its final composition to the Court. The National Task Force which is being constituted in pursuance of the above suggestion shall consist of the following members (names being set out in alphabetical order).

- (i) Dr Bhabatosh Biswas, Former Vice Chancellor, West Bengal University of Health Sciences, Kolkata;
- (ii) Dr Devender Singh Rana, Chairperson, Board of Management, Sir Ganga Ram Hospital, Delhi;
- (iii) Dr Devi Prasad Shetty, Chairperson and Executive Director, Narayana Healthcare, Bengaluru;
- (iv) Dr Gagandeep Kang, Professor, Christian Medical College, Vellore, Tamil Nadu;
- (v) Dr JV Peter, Director, Christian Medical College, Vellore, Tamil Nadu;
- (vi) Dr Naresh Trehan, Chairperson and Managing Director, Medanta Hospital and Heart Institute, Gurugram;
- (vii) Dr Rahul Pandit, Director, Critical Care Medicine and ICU, Fortis Hospital, Mulund (Mumbai, Maharashtra) and Kalyan (Maharashtra);
- (viii) Dr Saumitra Rawat, Chairman & Head, Department of Surgical Gastroenterology and Liver Transplant, Sir Ganga Ram Hospital, Delhi;

⁵ “Task Force”

- (ix) Dr Shiv Kumar Sarin, Senior Professor and Head of Department of Hepatology, Director, Institute of Liver and Biliary Science (ILBS), Delhi;
- (x) Dr Zarir F Udwadia, Consultant Chest Physician, Hinduja Hospital, Breach Candy Hospital and Parsee General Hospital, Mumbai;
- (xi) Secretary, Ministry of Health and Family Welfare, Government of India (*ex officio member*); and
- (xii) The Convenor of the National Task Force, who shall also be a member, will be the Cabinet Secretary to the Union Government. The Cabinet Secretary may nominate an officer not below the rank of Additional Secretary to depute for him, when necessary.

18 The Task Force is at liberty to draw upon the human resources of the Union Government for consultation and information, including the following:

- (i) A member of Niti Aayog to be nominated by the Vice-Chairperson;
- (ii) Secretary, Ministry of Home Affairs;
- (iii) Secretary, Department for Promotion of Industry and Internal Trade;
- (iv) Secretary, Ministry of Road Transport and Highways;
- (v) Director, All India Institute of Medical Sciences, New Delhi;
- (vi) Director General, Indian Council of Medical Research, New Delhi;
- (vii) Director General of Health Services; and
- (viii) Director General, National Informatics Centre; and
- (ix) Head, Centre for Development of Advanced Computing (C-DAC).

19 The concerned Secretaries shall be at liberty to nominate officers of the rank of Additional/Joint Secretary to depute for them. The Task Force is at liberty to formulate its modalities and procedure for working.

20 The Task Force may constitute one or more sub-groups on specialised areas or regions for assisting it, before finalising its recommendations. The Task Force may consider it appropriate to co-opt or seek the assistance of other experts within or outside government to facilitate its working, including in the following areas:

- (i) Infectious disease modelling;
- (ii) Critical care;
- (iii) Clinical virology/Immunology; and
- (iv) Epidemiology/Public health.

21 The *amicus curiae* appointed by this Court had tendered a list of experts on each of the above subjects ((i) to (iv) above in paragraph 20). In order to not constrain the discretion of the Task Force, we permit the Task Force to co-opt any one or more of the experts suggested by the *amicus curiae* or any other experts.

22 The Union Government and State Governments, Ministries, agencies and departments shall provide complete and real time data for facilitating the work of the Task Force as and when necessary. All private hospitals and other health care institutions shall co-operate with the Task Force.

23 The rationale for constituting a Task Force at a national level is to facilitate a public health response to the pandemic based on scientific and specialised domain knowledge. We expect that the leading experts in the country shall associate with the work of the Task Force both as members and resource persons. This will facilitate a meeting of minds and the formulation of scientific strategies to deal with an unprecedented human crisis. The establishment of this Task Force will enable the decision makers to have inputs which go beyond finding *ad-hoc* solutions to the present problems. The likely future course of the pandemic must be taken into contemplation at the present time. This will ensure that projected future requirements can be scientifically mapped in the present and may be modulated in the light of experiences gained. Estimating projected needs is crucial to ensure that the country remains prepared to meet future eventualities, which will cause a demand for oxygen, medicines, infrastructure, manpower and logistics. The establishment of the Task Force will provide the Union Government with inputs and strategies for meeting the challenges of the pandemic on a transparent and professional basis, in the present and in future. Bearing this in mind, we presently frame the following terms of reference for the Task Force. These terms can be modulated subsequently, as and when the need arises.

24 The terms of reference of the National Task Force shall be to:

- (i) Assess and make recommendations for the entire country based on the need for, availability and distribution of medical oxygen;
- (ii) Formulate and devise the methodology for the allocation of medical oxygen to the States and UTs on a scientific, rational and equitable basis;

- (iii) Make recommendations on augmenting the available supplies of oxygen based on present and projected demands likely during the pandemic;
- (iv) Make recommendations for the periodical review and revision of allocations based on the stage and impact of the pandemic;
- (v) Facilitate audits by sub-groups within each State and UT *inter alia* for determining:
 - (a) whether the supplies allocated by the Union Government reach the concerned State/UT;
 - (b) the efficacy of the distribution networks in distributing supplies meant for hospitals, health care institutions and others;
 - (c) whether the available stocks are being distributed on the basis of an effective, transparent and professional mechanism; and
 - (d) accountability in regard to the utilisation of the supplies of oxygen allocated to each State/UT;
- (vi) Review and suggest measures necessary for ensuring the availability of essential drugs and medicines;
- (vii) Plan and adopt remedial measures for ensuring preparedness to meet present and future emergencies which may arise during the pandemic;
- (viii) Facilitate the use of technology to ensure that the available manpower is optimised for implementing innovative solutions particularly in order to provide an outreach of expert medical care to rural areas;
- (ix) Suggest measures to augment the availability of trained doctors, nurses and para-medical staff including by the creation of suitable incentives;

- (x) Promote evidence based research to enhance effective responses to the pandemic;
- (xi) Facilitate the sharing of best practices across the nation to promote knowledge about the management of the pandemic and treatment of cases; and
- (xii) Generally, to make recommendations in regard to other issues of pressing national concern to find effective responses to the pandemic.

25 The purpose of conducting audits under item (v) of paragraph 24 is to ensure a measure of accountability for the proper distribution of oxygen supplies made available by the Union Government to the States/UTs. For the purpose of facilitating the audits under item (v) of paragraph 24 above, the Task Force will constitute sub-groups/committees for each State/UT comprising:

- (i) An officer of the State/UT Government not below the rank of Secretary to the State Government;
- (ii) An officer of the Union Government not below the rank of Additional/Joint Secretary;
- (iii) Two medical doctors in the State/UT concerned including at least one with administrative experience of managing the medical facilities of a hospital; and
- (iv) A representative from the Petroleum and Explosives Safety Organisation (PESO).

For carrying out the above audit exercise for NCTD, the audit sub-group shall consist of:

- (i) Dr Randeep Guleria, Professor and Head, Department of Pulmonary Medicine and Sleep, AIIMS;
- (ii) Dr Sandeep Budhiraja, Clinical Director & Director – Internal Medicine, Max Healthcare; and
- (iii) An IAS officer, each from the Union Government and GNCTD, not below the rank of Joint Secretary.

26 We emphasise that the purpose of conducting audits is to ensure accountability in respect of the supplies of oxygen provided to every State/UT. The purpose is to ensure that the supplies which have been allocated are reaching their destination; that they are being made available through the distribution network to the hospitals or, as the case may be, the end users efficiently and on a transparent basis; and to identify bottlenecks or issues in regard to the utilization of oxygen. The purpose of the audit is not to scrutinise the decisions made in good faith by doctors while treating their patients.

27 The Union Government shall continue with the present practice of making allocations of oxygen (as modified by the orders of this Court or the orders of the High Courts as the case may be) until the Task Force has submitted its recommendations in regard to proposed modalities. The Union Government shall on receipt of the recommendations of the Task Force take an appropriate decision in regard to the allocation of oxygen and on all other recommendations. The Task Force shall also submit its recommendations from time to time to this Court. We request the Task Force to commence work immediately, taking up the pressing issue of determining the modalities for oxygen expeditiously within a

week. The tenure of the Task Force shall be six months initially. The Union Government shall provide all necessary assistance to the Task Force and nominate two Nodal Officers to facilitate its work. The Nodal Officers shall also arrange for logistics, including communication with the members and arranging the virtual meetings, of the Task Force.

28 The proceeding shall be listed before this Court on 17 May 2021.

(SANJAY KUMAR-I)
AR-CUM-PS

(SAROJ KUMARI GAUR)
COURT MASTER

State/UT-wise allocation of Covishield and Covaxin through GoI**for 1st fortnight of May'21****191**

S. No.	State	Covishield	Covaxin	Total
1	Andaman & Nicobar Islands	19,940	-	19,940
2	Andhra Pradesh	6,90,360	2,27,490	9,17,850
3	Arunachal Pradesh	36,510	-	36,510
4	Assam	2,53,960	83,690	3,37,650
5	Bihar	7,64,850	2,52,040	10,16,890
6	Chandigarh	32,210	-	32,210
7	Chhattisgarh	6,47,300	2,13,300	8,60,600
8	Dadra & Nagar Haveli	8,300	-	8,300
9	Daman & Diu	7,910	-	7,910
10	Delhi	3,73,760	1,23,170	4,96,930
11	Goa	54,620	-	54,620
12	Gujarat	12,48,700	4,11,490	16,60,190
13	Haryana	4,23,890	1,39,690	5,63,580
14	Himachal Pradesh	3,02,080	-	3,02,080
15	Jammu & Kashmir	3,84,700	-	3,84,700
16	Jharkhand	2,62,790	86,590	3,49,380
17	Karnataka	10,05,370	3,31,300	13,36,670
18	Kerala	6,84,070	2,25,430	9,09,500
19	Ladakh	15,260	-	15,260
20	Lakshadweep	4,160	-	4,160
21	Madhya Pradesh	8,71,290	2,87,120	11,58,410
22	Maharashtra	17,50,620	5,76,890	23,27,510
23	Manipur	31,590	-	31,590
24	Meghalaya	42,520	-	42,520
25	Mizoram	45,550	-	45,550
26	Nagaland	30,220	-	30,220
27	Odisha	5,88,010	1,93,770	7,81,780
28	Puducherry	29,890	-	29,890
29	Punjab	4,63,710	1,52,810	6,16,520
30	Rajasthan	12,92,460	4,42,390	17,34,850
31	Sikkim	31,600	-	31,600
32	Tamil Nadu	5,39,060	1,94,120	7,33,180
33	Telangana	6,28,760	2,07,200	8,35,960
34	Tripura	96,670	31,860	1,28,530
35	Uttar Pradesh	13,49,850	4,11,870	17,61,720
36	Uttarakhand	2,42,160	79,800	3,21,960
37	West Bengal	9,95,300	3,27,980	13,23,280

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**State/UT-wise availability of 150 lakh doses of Covishield and 50 lakh doses of Covaxin
for procurement through 'Other than Govt. of India Channel' in May 21**

S. No.	State	Available for procurement: 2 cr doses	Available for procurement: 1.5 cr doses of Covishield	Available for procurement: 50 lakh doses of Covaxin
1	Andaman & Nicobar Islands	9,070	9,070	-
2	Andhra Pradesh	13,35,630	9,91,700	3,43,930
3	Arunachal Pradesh	20,180	20,180	-
4	Assam	5,00,310	3,71,480	1,28,830
5	Bihar	16,01,700	11,89,250	4,12,450
6	Chandigarh	33,000	33,000	-
7	Chhattisgarh	4,00,150	2,97,110	1,03,040
8	Dadra & Nagar Haveli	7,480	7,480	-
9	Daman & Diu	6,050	6,050	-
10	Delhi	3,60,530	2,67,690	92,840
11	Goa	32,870	32,870	-
12	Gujarat	9,67,890	7,18,650	2,49,240
13	Haryana	4,30,130	3,19,370	1,10,760
14	Himachal Pradesh	1,07,620	1,07,620	-
15	Jammu & Kashmir	1,84,950	1,84,950	-
16	Jharkhand	5,21,960	3,87,560	1,34,400
17	Karnataka	9,48,220	7,04,050	2,44,170
18	Kerala	5,34,290	3,96,710	1,37,580
19	Ladakh	5,000	5,000	-
20	Lakshadweep	1,250	1,250	-
21	Madhya Pradesh	12,17,770	9,04,190	3,13,580
22	Maharashtra	18,60,730	13,81,580	4,79,150
23	Manipur	39,840	39,840	-
24	Meghalaya	42,630	42,630	-
25	Mizoram	16,340	16,340	-
26	Nagaland	36,580	36,580	-
27	Odisha	6,44,420	4,78,480	1,65,940
28	Puducherry	30,010	30,010	-
29	Punjab	4,43,470	3,29,280	1,14,190
30	Rajasthan	11,37,720	8,44,750	2,92,970
31	Sikkim	9,940	9,940	-
32	Tamil Nadu	10,35,060	7,68,530	2,66,530
33	Telangana	3,90,590	2,90,010	1,00,580
34	Tripura	58,820	43,670	15,150
35	Uttar Pradesh	34,38,850	25,53,340	8,85,510
36	Uttarakhand	1,64,550	1,22,180	42,370
37	West Bengal	14,24,400	10,57,610	3,66,790
	India	2,00,00,000	1,50,00,000	50,00,000



भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण बोर्ड
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Government of India
Department of Health and Family Welfare
Ministry of Health and Family Welfare

राजेश भूषण, आईएएस
सचिव

RAJESH BHUSHAN, IAS
SECRETARY

Annexure R/6

D.O. No. 1920764/2020-Imm.
23rd April, 2021

Dear Colleague,

As you are aware, the Ministry has issued the Liberalised Pricing and Accelerated National Covid-19 Vaccination Strategy for further accelerating the pace of COVID-19 vaccination. The said Strategy Document is available at – <https://www.mohfw.gov.in/pdf/LiberalisedPricingandAcceleratedNationalCovid19VaccinationStrategy2042021.pdf>.

In view of the expansion of the cohort of eligible beneficiaries with inclusion of citizens aged 18 years to 44 years, for vaccination in private sector vaccination centers, the States/UTs would have to make the necessary preparations, well in advance, to ensure that the eligible citizens are able to access the vaccination services seamlessly and conveniently. Since, the cohort of eligible beneficiaries has been significantly enhanced, suitable arrangements must be made to avoid overcrowding and consequent law and order situations, at the vaccination centers. In this context, following decisions are clarified for facilitating systematic implementation of phase III of the vaccination drive from 1st May, 2021 –

1. Registration of COVID Vaccination Centers (CVCs):

1.1. It will continue to be mandatory for all Government and Private COVID Vaccination Centers (CVCs) to register on the CoWIN system, regardless of the source of vaccine doses. It shall also be mandatory for all CVCs to record all vaccinations, issue digital vaccination certificates and to report all AEFIs on the CoWIN system.

1.2. The eligibility conditions for any health facility for registration as a CVC also remain unchanged. For any Private Health Facility to be operated as a CVC, the facility must have the following –

1. Sufficient Cold Chain equipment and capacity.
2. Sufficient rooms/space for waiting area, vaccination and observation post vaccination.
3. Sufficient number of trained vaccinators and verifiers
4. Ability to manage the Adverse Events Following Immunization (AEFI), as per the norms and guidelines of the Ministry.

1.3. Registration of Industrial Establishment CVCs:

1. Wherever an Industrial Establishment has a hospital that is eligible for registration as a CVC as per the eligibility conditions given in para 1.2, such Industrial Establishment Hospital can be registered on CoWIN as an Industrial Establishment CVC.

....contd/-

2. The Industrial Establishments without such suitable hospital may be registered as an Industrial Workplace CVC, with mapping to any other existing private CVC.
 - 1.4. Henceforth, it will not be necessary for the State/UT Governments to send any proposals to the Ministry for approval of new private CVCs, prior to their registration on CoWIN. The State/UT Government may designate an appropriate Authority at State/District level that will ensure that only facilities eligible as per the criteria specified in para 1.2 above, are registered on CoWIN as a CVC. The Designated Authority must take a decision on registration, with in two days of the receipt of application/request in this regard.
 - 1.5. Registration of CVCs, on the CoWIN system, will continue to be done by the District Immunization Officer.
 - 1.6. There will be no need for the existing private CVC, which is already on CoWIN, to re-register on the COWIN system.
2. **Procurement of vaccine doses and declaration of stocks and prices:**
 - 2.1. The private hospitals and industrial establishments (through their hospitals), willing to provide vaccination services, may procure vaccine doses from the manufacturers, through their hospitals, exclusively from the 50% supply earmarked for other than Govt. of India channel.
 - 2.2. Each private CVC, including the already registered CVCs, must declare on CoWIN, the vaccine type(s), the stocks of vaccines and the prices decided by the CVC to be charged to the citizens, for vaccination services being offered 1st May 2021 onwards. Appropriate changes are being done in the facility registration module of CoWIN to include these informations.
 - 2.3. The vaccine types and theirs prices will be displayed in the "Appointments" module on CoWIN so that the citizens can make an informed choice at the time of booking a vaccination appointment.
 - 2.4. The private CVCs will be able to populate their schedule for offering appointment slots for citizens only after the requisite information as mentioned in para 2.2 has been declared on CoWIN.
 - 2.5. All vaccination slots at private CVCs will continue to be offered only for online appointment from CoWIN or Arogya Setu. On-site registration/appointments will be allowed only, if any doses are left in the last opened vial(s) so as to minimize vaccine wastages.
 - 2.6. The provisions of para 2.5 will not be applicable to Industrial Establishment CVCs and Workplace CVCs when these CVCs are operated exclusively for a defined group (for example for employees of an industrial establishment etc.).

3. Eligibility of beneficiaries:

- 3.1. As provided in the Strategy Document, all priority groups, such as the Health Care Workers, the Front-Line Workers and citizens above aged 45 years or more (as on 01.01.2022), shall continue to be eligible for vaccination –
 1. Free of cost from the Government CVCs; or
 2. On payment from the private CVCs.
- 3.2. The State/UT Governments, in the event of procurement of vaccine doses directly from the manufacturers, may decide to expand the coverage from the doses so procured to reduce the cut off age for eligibility for vaccination at the Government CVCs. The CoWIN system shall provide the feature to States/UTs for setting the minimum age cut off value for a State/UT. In such cases the Government CVCs will be visible to eligible beneficiaries for booking an online appointment based on validation on the minimum cut off age defined by the respective State/UT Government.
- 3.3. Citizens in the age group of 18 years to 44 years shall be eligible to receive vaccination, on payment, from any of the private CVCs. Citizens below the age of 45 years shall also be eligible to receive vaccination from a Government CVC in a State/UT where that State/UT decides to lower the minimum cut off age for eligibility of beneficiaries to less than 45 years, for covering such additional eligible beneficiaries from the vaccine stocks directly procured by the respective State/UT Government from vaccine manufacturers.

4. Registration and appointment of expanded cohort (18-44 years of age as on 01.01.2022):

- 4.1. Registration of citizens in 18-44 age group will start with only online registration on CoWIN from 28.04.2021 (Wednesday) onwards.
- 4.2. The online appointment facility will also be offered from 28.04.2021 (Wednesday) for such citizens for booking appointments for sessions and slots available on CoWIN for vaccination from 01.05.2021 (Saturday) onwards.

In view of the above, the States/UTs are advised to take the following actions immediately –

1. Registration of the new CVCs may be taken up in campaign mode. Meetings may be held with private hospitals and their representative organizations in which they may be fully informed about the Liberalised Pricing and Accelerated National Covid-19 Vaccination Strategy and above provisions, as well as how these provisions will be implemented.
2. Registration of willing hospitals meeting the eligibility criteria may be done on CoWIN on an expeditious basis. Subsequent of registration, user credentials for CoWIN may be provided to the newly registered private CVCs without any delay. Trainings may also be provided to the staff proposed to be used as vaccinators, arrangements at such CVCs, norms for social distancing, COVID Appropriate Behaviour and for AEFI management protocols as per the Guidelines of the Ministry.

3. The new version of CoWIN software is being prepared for implementation of the revised protocols. In the meanwhile, trainings for the CVC site managers and verifiers and vaccinators may be planned for use of CoWIN. Such training schedule may be shared by States/UTs at covid19vaccine.mohfw@gmail.com.
4. Adequate publicity in all forms of media may be ensured to create awareness among citizens that the vaccination services to citizens in the age group of 18 to 44 years is initially being offered only through online self-registration and appointments through CoWIN (cowin.gov.in) and Arogya Setu and that there would be no facility for on-site (walk-in) registration for such beneficiaries initially.
5. The system of supplying vaccine stocks to private CVCs and collection of Rs. 150 per dose, will cease to exist from 1st May 2021. State/UT Government would therefore need to do a complete stock taking of the funds deposited by the Private CVCs, the vaccine doses supplied to them, the vaccine doses utilized so far and the doses likely to be utilized till 30th April 2021. Any unutilized vaccine stocks, balance as on April 30th 2021, will have to be returned to the Cold Chain Point from where the stocks were issued. The State/UT Governments must make a careful assessment of the potential for full utilization of such vaccine doses up to 30th April 2021, before issuing any further stocks to the private CVCs.
6. All States/UTs must closely coordinate with law & order authorities for the first week beginning from 1st May 2021 in respect of crowd management at private CVCs.

I look forward to successful implementation of the Liberalised Pricing and Accelerated National Covid-19 Vaccination Strategy in your State/UT.

Warm Regards.

Yours sincerely



(Rajesh Bhushan)

Additional Chief Secretary/ Principal Secretary/ Secretary, Health - All States/UTs

COVID-19 Vaccination of Persons without prescribed Identity Cards through CoWIN

1. India's National Covid-19 Vaccination Strategy is based on scientific and epidemiological evidence and focuses on systematic end-to-end planning. Phase-I of the National Covid-19 Vaccination Strategy was launched on 16th January 2021 and focussed on protecting Health Care Workers (HCWs) and Front Line Workers (FLWs). Phase-II was initiated from 1st March 2021 and 1st April 2021 and focussed on protecting the most vulnerable i.e. population more than 45 years of age. Liberalised Pricing and Accelerated National Covid-19 Vaccination Strategy came in effect from 1st May 2021 under which COVID-19 Vaccination was opened for persons 18-44 years of age groups.
2. In all these phases, it has been prescribed that the beneficiary must either self-register or be registered in Co-WIN portal and that the identity and eligibility of the beneficiary be verified by vaccinator through one of the following seven prescribed individual Photo ID Proof prior to vaccination, namely –
 - i. Aadhar Card
 - ii. Electoral Photo Identity Card (EPIC) - Voter ID
 - iii. Passport
 - iv. Driving License
 - v. PAN Card
 - vi. NPR Smart Card
 - vii. Pension Document with photograph.
3. Ministry is cognizant of the need for facilitating COVID-19 vaccination for all people, and especially the vulnerable groups who may not possess any of the seven prescribed Identity Cards. The Ministry has also received several representations from various state governments and agencies/organizations regarding COVID-19 Vaccination of such people who do not have any of the seven prescribed Identity Cards, required for verification before vaccination.
4. In this context, there is need to provide special consideration to vulnerable population of the country, as these beneficiaries are also at risk of exposure to COVID-19 infection and the consequent sequelae and outcomes of the disease, during the pandemic. Further they may not have any official Photo ID card like other citizens, but COVID-19 Vaccination services may not be denied in absence of Identity Proofs.
5. In view of the above, following procedure, developed in consultation with the technical experts, is hereby prescribed for providing vaccination coverage to people who do not possess any of the seven Identity Cards prescribed for availing COVID vaccination services–
 - i. Such groups of people include nomads (including sadhu/saints from various religions), prison inmates, inmates in Mental Health Institutions, citizens in Old Age Homes, road side beggars, people residing in rehabilitation

centres/camps and any other identified eligible persons, aged 18 years or more, and not having any of the seven prescribed individual Photo ID Cards.

- ii. District Task Force may identify such groups of persons in respective districts not having any of the prescribed individual Photo ID Cards with assistance from concerned government department/ organisation like department of minority affairs, social justice, social welfare etc.
- iii. The information regarding the identified groups and the number of beneficiaries to be covered, must be collated at the state level and the state government must issue clear instructions for implementation of these SOPs along with the district-wise estimated maximum number of doses to be administered using this special dispensation. A copy of such instructions must be displayed in public domain and should also be endorsed to the Ministry.
- iv. A Key Facilitator may also be identified for each such group. The Key Facilitator must have a valid and active mobile phone and must also have at least one of the seven mandated ID cards. These could be officials of the institutions (both public or private) which normally provide care and services to people in the identified groups, e.g. Prison officials for prison inmates, Executive Officer/Superintendent of and Old Age Home etc.
- v. A district nodal officer may be designated by the DTF, for identification of Key Facilitators, preparation of vaccination plan, identification of CVCs where vaccination sessions are to be organised, preparation of vaccination schedule, communication of vaccination schedule to the identified groups/beneficiaries and mobilization of beneficiaries as per vaccination plan.
- vi. District Immunization Officer (DIO) will be responsible for organization of vaccination sessions at identified CVCs for providing coverage to the identified groups.
- vii. The CoWIN system will provide the facility for creation of special vaccination sessions for this purpose. The session will have following features –
 - i. Registration of as many beneficiaries as are to be covered (subject to the limit of session capacity), without mandatory capturing of Mobile Number and Photo ID Card, through facilitated cohort registration.
 - ii. All vaccination slots in such special sessions will be reserved for vaccination of such facilitated cohorts.
 - iii. This facility will only be available at government CVCs.
 - iv. Information such as name, year of birth (as provided by the beneficiary) and gender will be entered in the CoWIN system for the beneficiaries.
 - v. The Key Facilitator shall verify the identity of the beneficiaries.
 - vi. Digital vaccination certificates are to be provided to the beneficiaries, preferably at the Vaccination Center itself.
- viii. The District Nodal Officer will be personally responsible to ensure that the special dispensation provided through these instructions, is extended only to

cover such persons who do not have any of the seven mandated Photo ID Cards.

- ix. Vaccine doses made available through the Government of India channel may be used for vaccination of beneficiaries aged 45 years or more and the vaccine doses procured by the State/UT Government may be used for those aged 18 years to 44 years.
- x. All technical protocols as prescribed in the Guidelines of the Ministry regarding vaccination centres and AEFI management etc., must be followed.

Annexure – “R-6”**Allocation and Supply of Remdesivir till 07.05.2021**

S No.	State/UT	Allocation dated 01.05.2021 for the period from 21st April to 9th May 2021	Total supplies made from 21st April to 7th May	Latest Allocation dated 07.05.2021 for the period from 21st April to 16th May
1	Andaman and Nicobar Islands	2000	2000	2000
2	Andhra Pradesh	142100	179311	235000
3	Arunachal Pradesh	2000	2070	2000
4	Assam	13800	15533	31000
5	Bihar	87800	83517	150000
6	Chandigarh	8900	11239	13000
7	Chhattisgarh	130900	133157	200000
8	Dadra and Nagar Haveli and Daman and Diu	3400	1028	4000
9	Delhi	150900	167826	220000
10	Goa	10700	12271	26000
11	Gujarat	307000	350387	419000
12	Haryana	84800	84734	149000
13	Himachal Pradesh	9300	23234	24000
14	Jammu and Kashmir	20800	16038	42000
15	Jharkhand	46900	54446	79000
16	Karnataka	301300	283132	575000
17	Kerala	109300	63626	200000
18	Ladakh	2000	1500	2000
19	Lakshadweep	2000	500	2000
20	Madhya Pradesh	189700	197396	260000
21	Maharashtra	809500	748974	1157000
22	Manipur	2000	2225	2000
23	Meghalaya	2000	2310	2000
24	Mizoram	2000	2000	2000
25	Nagaland	2000	220	2000
26	Odisha	34700	31918	73000
27	Puducherry	5100	5268	11000
28	Punjab	50000	53913	85000
29	Rajasthan	141600	139772	248000
30	Sikkim	2000	1230	2000
31	Tamil Nadu	135500	168869	205000
32	Telangana	93800	169225	145000
33	Tripura	2000	1645	2000
34	Uttarakhand	41600	40926	74000
35	Uttar Pradesh	336200	254413	495000
36	West Bengal	94400	79627	160000

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37	Allocation for Central Government Institutions	70000	11377	70000
	Total	3450000	3396857	5370000

Annexure – R-7**Allocation and Supply of Tocilizumab till 07.05.2021**

S No.	State/UT	Latest Allocation dated 30.04.2021	Total Supplies made against requisition from 27th April to 7th May
1	Andhra Pradesh	280	50
2	Bihar	270	150
3	Chhattisgarh	340	200
4	Delhi	500	513
5	Goa	50	50
6	Gujarat	370	370
7	Haryana	240	240
8	Himachal Pradesh	45	45
9	Jammu and Kashmir	60	50
10	Jharkhand	145	75
11	Karnataka	855	294
12	Kerala	705	200
13	Madhya Pradesh	275	275
14	Maharashtra	1960	1755
15	Odisha	135	126
16	Puducherry	25	25
17	Punjab	200	318
18	Rajasthan	440	439
19	Tamil Nadu	315	385
20	Telangana	210	65
21	Uttarakhand	125	100
22	Uttar Pradesh	870	280
23	West Bengal	285	213
24	Allocation for Central Government Institutions including UTs and NER	1200	260
Total		9900	6478

Annexure- “R-8”Result of Survey of Chemist shops conducted across country on 03/05/2021

A survey of availability of Hydroxy-chloroquine tabs, Methyl Prednisolone inj., Enoxaprine inj., Dexamethasone and Paracetamol tablets across India done in Chemist Shops at various localities by the office of DCGI on 03.05.2021. Availability details are as under

- Total number of chemist shop surveyed = **370**
- Number of shops surveyed v/s availability of HCQ tablets in shops near COVID-19 designated hospitals = **91/105 (86.66%)**
- Number of shops surveyed v/s availability of Methyl prednisolone inj. in shops near COVID-19 designated hospitals = **78/105 (74.28%)**
- Number of shops surveyed v/s availability of Enoxaprine inj. in shops near COVID-19 designated hospitals = **61/105 (71.59%)**
- Number of shops surveyed v/s availability of Dexamethasone in shops near COVID-19 designated hospitals = **84/105 (80.00%)**
- Number of shops surveyed v/s availability of HCQ tablets in general chemist shops including orthopedic hospitals = **213/265 (80.37%)**
- Number of shops surveyed v/s availability Methyl prednisolone inj. in general chemist shops including orthopedic hospitals = **123/265 (46.41%)**
- Number of shops surveyed v/s availability of Enoxaprine inj. in general chemist shops including orthopedic hospitals = **99/265 (37.35%)**
- Number of shops surveyed v/s availability of Dexamethasone in general chemist shops including orthopedic hospitals = **198/265 (74.71%)**
- Number of shops surveyed v/s availability of Paracetamol tablets = **354/370 (95.67%)**

Annexure R/10

File No. ED/Misc-273/2020-3

Government of India

Directorate of Health Services

Central Drugs Standard Control Organization

(Enforcement Division)

205

FDA Bhawan Kotla Road

New Delhi – 110 002

Dated 10.04.2021

To

All State/UT Drugs Controllers

Subject: Enforcement activities to stop hoarding/black marketing/overcharging of COVID management drug Remdesivir - Regarding

Sir/Madam

It has been brought to the notice of this office that many family members of COVID-19 patients have raised concerns highlighting that Remdesivir is once again being sold above MRP and in some cases as high as over 10 times.

In light of reports of shortages of Remdesivir Ministry of Health and Family Welfare, Government of India have also communicated to the State/UT Governments regarding various steps initiated including direction already given to enforcement staff/Drugs Inspectors to verify stocks and check other malpractices and also take other effective action to curb hoarding and black marketing with request to review this with the Drugs Inspectors in the States/UTs.

In view of above, you are requested to instruct your 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 the special drive of monitoring and investigation, so that any such incidence for the drug is prevented.

Action taken in the matter may please be intimated to this office at the earliest.

Yours Faithfully


(Dr. V. G. Soman)
Drugs Controller General (India)

Copy to:

1. All Zonal/SubZonal offices of CDSCO – For immediate action in the matter

Copy for information to:

1. Chairman, NPPA
2. PS to JS (R), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi – 110 011

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Dr.V. G. Somani

Drugs Controller General (India)

Central Drugs Standard Control Organisation

Directorate General of Health Services

Ministry of Health & Family Welfare

Government of India

FDA Bhawan, Kotla Road,

New Delhi- 110002 (India)



डॉ. वी. जी. सोमानी
 औषधी महानियंत्रक (भारत)
 केंद्रीय औषधि मानक नियंत्रण संगठन
 स्वास्थ्य एवं परिवार कल्याण मंत्रालय
 भारत सरकार
 एफ.डी.ए. भवन, कोटला रोड,
 नई दिल्ली-110002

Date: 24.04.2021

No. ED/Misc-273/2020-3

Dear sir/madam,

As you may be aware, this office has already written to you letter dated 10.04.2021 (Copy enclosed) and subsequent letters requesting stringent action against hoarding/black marketing/overcharging for various drugs including Remdesivir, Favipiravir, etc. CDSCO is regularly following up the matter with your goodself to prevent any such activities in the country.

However, there are reports in media and other various fora regarding hoarding/black marketing/overcharging of various drugs including Remdesivir, Favipiravir, etc. Serious concerns are being raised in this regard at various levels of the government as well as in various courts and undersigned has been asked to attend this matter alongwith SDCs of States/UTs.

You are therefore again requested to instruct your enforcement staff immediately to keep strict vigil especially at sensitive places and to take stringent action against hoarding/black marketing/overcharging of drugs, by conducting the special drive of monitoring and investigation, so that any such incidence of drugs is prevented. This exercise shall be undertaken daily till it is completely resolved.

There should be zero tolerance for any kind of hoarding/black marketing/overcharging of such drugs. You may establish a special task force for the purpose and also nominate a nodal officer in your state/UT to attend all the complaints & intelligence information in this regard. The name, mobile number and email id of nodal officer shall be informed to this office.

Dr. P.B.N. Prasad, JDC (I), CDSCO (HQ) is nominated as nodal officer from CDSCO (Email id: pbn.prasad@cdsco.nic.in and Mobile: +91 9703988270, Landline: 011-23502913) for coordination.

Action taken in the matter may please be intimated to this office on daily basis as per format given vide letter of even number dated 20.04.2021 (copy enclosed) on vgsjdc@gmail.com, pbn.prasad@cdsco.nic.in, enforcecell.div@cdsco.nic.in, newdrugs2018@cdsco.nic.in and dci@nic.in.

Non receipt of daily report is undesirable, so kindly attend it on top priority.

Yours Sincerely

V.G.S.

(Dr. V. G. Somani)
 Drugs Controller General (India)

To,

All State/UT Drugs Controllers

Copy to:

1. All Zonal/SubZonal offices of CDSCO – For active coordination with the SDCs for taking the enforcement action

Copy for information to:

1. PS to JS (R), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi – 110 011

File No. ED/Misc-273/2020-3
 Government of India
 Directorate of Health Services
 Central Drugs Standard Control Organization
 (Enforcement Division)

FDA Bhawan Kotla Road
 New Delhi – 110 002
 Dated 27.04.2021

To

All State/UT Drugs Controllers

Subject: Enforcement activities to stop hoarding/black marketing/overcharging of COVID management drug Remdesivir, Favipiravir, Tocilizumab etc., - Regarding

Sir/Madam,

Please refer to my D.O. letter No. ED/Misc-273/2020-3 dated 24.04.2021 (Copy enclosed) requesting you to take stringent action against hoarding/black marketing/overcharging for various drugs including Remdesivir, Favipiravir, Tocilizumab etc.

However, cases of hoarding/black marketing/overcharging of Remdesivir etc., are continued to be reported in media and other various fora. Therefore, serious concerns are being raised in this regard at various levels of the government as well as in various courts.

You are therefore again instructed to immediately take strict steps and action to stop the hoarding/black marketing/overcharging of drugs, by conducting the special investigation drive, so that any such incidence of drugs is prevented. This exercise has to be undertaken daily till it is completely resolved.

As communicated earlier, there should be zero tolerance for any kind of hoarding/black marketing/overcharging of such drugs. You might have established a special task force for the purpose with nodal officer in your state/UT to attend all the complaints & intelligence information in this regard. Dr. P.B.N. Prasad, JDC (I), CDSCO (HQ) has been nominated as nodal officer from CDSCO (Email id: pbn.prasad@cdsco.nic.in and Mobile: +91 9703988270, Landline: 011-23502913) for coordination.

Action taken in the matter may please be intimated to this office on daily basis as per format given vide letter of even number dated 20.04.2021 (copy enclosed) on vgsidci@gmail.com, pbn.prasad@cdsco.nic.in, enforcecell.div@cdsco.nic.in, newdrugs2018@cdsco.nic.in and dci@nic.in.

Daily reporting in this regard is absolutely necessary to address the challenges for ensuring smooth availability of Remdesivir and other drugs to supplement the efforts of government to tackle this pandemic situation.

Non receipt of daily report is undesirable, so kindly attend it on top priority.

Yours Sincerely


 (Dr. V. G. Somani)
 Drugs Controller General (India)

Copy to:

1. All Zonal/SubZonal offices of CDSCO – For immediate action in the matter

Copy for information to:

2. Chairman, NPPA
 3. PS to JS (R), Ministry of Health and Family Welfare, NirmanBhawan, New Delhi – 110 01



Dear Colleague,

No.X.11035/130/2021-DRS
Dated the 7th May, 2021

You may be aware that a number of complaints regarding black marketing and hoarding of Remedisivir Injection and other essential medicines required for the treatment of Covid-19 patients have been received by the Government. Action on such complaints relating to profiteering, hoarding etc. are being carried out by the Office of Drugs Controller General (India) (DCGI). The DCGI has also directed the State Drug Controllers to take swift and effective action on such complaints vide the letters No. ED/Misc-273/2020-3, dated 10.04.21, 24.04.21 and 27.04.21. Copies of these letters are attached for ready reference.

2. Further, the Hon'ble Supreme Court of India vide its interim orders dated 30th April, 2021 in Suo Motu Writ Petition (Civil) No. 3 of 2021, amongst others, took note of several critical drugs used for treatment of Covid 19 being sold at significantly inflated prices and has directed the Government to consider constituting a special team to identify and prosecute those who sell medical grade oxygen/ covid-19 medicines at exorbitant prices, sell fake substances and recover the concerned substances. It further directed the Central Government to consider creating a platform for easy reporting and redressal of such cases.

3. The 'Drugs' are defined and regulated under the Drugs and Cosmetics Act 1940. The 'Drugs' as defined under the Drugs and Cosmetics Act, 1940, are also treated as essential commodities under the Essential Commodities Act, 1955. The regulatory control over the manufacture and sale of drugs is exercised by the State Licensing Authorities appointed by the State Governments under the provisions of the Drugs and Cosmetics Act, 1940.

4. As such, in order to ensure availability and accessibility of drugs and other medical products used for treatment of Covid-19, I would like to request you to look into to the matter and initiate appropriate action for taking all necessary measures to stop black marketing/ hoarding etc. by using the powers available under provisions of Drugs & Cosmetics Act, Prevention of Black Marketing and Maintenance of Supplies of Essential Commodities Act etc., as well as other applicable rules and regulations.

Encl: As above

warm regards

Yours sincerely,



(Vikas Sheel)

To,

The Additional Chief Secretary/ Principal Secretary/ Secretary, Health - All States/UTs

एड्स - जानकारी ही बचाव है

Talking about AIDS is taking care of each other

www.mohfw.nic.in

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Copy to:

Drugs Controller General (India), Central Drugs Standard Control Organization, FDA
Bhawan, New Delhi



A handwritten signature in black ink, appearing to read "Lalit". Below the signature, the date "7/5/21" is written vertically.



Annexure R/11



LAV AGARWAL, IAS
Joint Secretary

Tel. : 011-23061195
T/Fax : 011-23061842
E-mail : alav@ias.nic.in

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली - 110011

GOVERNMENT OF INDIA

MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI - 110011

F. No. COVID-19/60/2020-ME(Pl.1)
Dt. 06 August, 2020



Dear Madam / Sir,

As you are aware, healthcare workers are in the fore-front of COVID management. One of the occupational hazards is risk of exposure and acquiring the disease. Advisory has already been issued on risk assessment and categorization of doctors and other healthcare workers exposed to COVID and categorizing them as high risk and low risk exposures (<https://www.mohfw.gov.in/pdf/updatedAdvisoryforManagingHealthcareworkersworkinginCOVIDandNonCOVIDareasofthehospital.pdf>).

2. Persons with high risk exposure to the virus while performing COVID duty are required to undergo quarantine initially for one week only. Thereafter, taking profile of such healthcare workers, a decision shall be taken by institution to extend quarantine for a further period of one week. This quarantine has been prescribed in larger public interest to stop spread of the disease.

3. During a hearing held on 31.07.2020 in the Hon'ble Supreme Court in WP(C) No. 759/2020-Dr. Arushi Jain vs. UoI and others, it was pointed out that in some cases doctors and health workers, who are quarantined, their period of quarantine is being treated as on leave.

4. The matter has since been considered by this Ministry in consultation with Department of Personnel and Training, Govt. of India, and it has been decided that the quarantine period of doctors and health workers needs to be treated as 'on duty'.

5. All concerned may accordingly be directed to ensure that quarantine period of Doctors and health workers for their duties related to COVID-19 shall be treated as 'on duty' only.

With regards,

Yours sincerely,

(Lav Agarwal)

To,

1. ACSS/Pr. Secretaries/Secretaries (Health) of all States/UTs
2. Directors of all AIIMS
3. Directors / MS of all Central Government Hospitals

Please circulate to all HODs with instruction to inform all HCW working under them, Nursing Superintendent (for circulation in different nursing areas, DDA, Registrar PG2-

7, 8/2020

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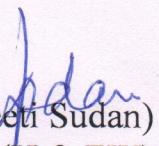
No. COVID-19/60/2020-ME(Pt.I)
Government of India
Ministry of Health and Family Welfare
(Medical Education Division)

Nirman Bhawan, New Delhi
Dated: 18th June, 2020

ORDER

Pursuant to the order of the Hon'ble Supreme Court in a batch of Writ Petitions and interim application [Writ Petition (Civil) 10795/2020, 10830 & 10852 & IA 48951 of 2020)] and in exercise of powers delegated under section 10(2) of the Disaster Management Act 2005 vide order No.40-2/2020-DM-I(A) dated 11th March 2020, it is hereby directed that the States and Union Territory Administration should ensure that salaries of doctors and health workers doing COVID-19 related duty shall be released on time.

The Chief Secretary of the States/UTs should ensure compliance of this order by all concerned, violation of which will be treated as an offence under the Disaster Management Act read with the Indian Penal Code, and action taken accordingly against defaulting hospitals / institutions / authorities.


(Preeti Sudan)
Secretary (H & FW)

Chief Secretaries of all States/UTs
Directors of AIIMS
Directors/MS of all Central Government hospitals.

Copy to

Solicitor General of India
Registrar, Supreme Court

Ministry of Health & Family Welfare
Directorate General of Health Services
(EMR Division)

Advisory for managing Health care workers working in COVID and Non-COVID areas of the hospital

1. Background

The health care personnel working in hospitals are at increased risk of acquiring the COVID-19 disease, if there is a breach in the personal protection while managing patients.

The health-work force is a valuable and scarce resource. Large number of COVID-19 affected health personnel getting isolated for treatment and their close contacts undergoing quarantine affects the health/hospital service delivery.

2. Purpose of the document

The purpose of the document is to provide guidance on preventive measures, isolation and quarantine of health care functionaries.

3. Institutional Mechanism for preventing and responding to Healthcare Associated Infections (HAIs) among HCWs

Hospitals shall activate its Hospital Infection Control Committee (HICC).The HICC in the health facility is responsible for implementing the Infection Prevention and Control (IPC) activities and organizing regular trainings on IPC for HCWs.

A Nodal Officer (Infection Control Officer) shall be identified by each hospital to address all matters related to Healthcare Associated Infections (HAIs). With reference to preventing such infection among healthcare workers, he/she will ensure that:

- i. Healthcare workers in different settings of hospitals shall use PPEs appropriate to their risk profile as detailed in the guidelines issued by this Ministry (available at:
<https://www.mohfw.gov.in/pdf/GuidelinesonrationaluseofPersonalProtectiveEquipment.pdf> and
<https://www.mohfw.gov.in/pdf/UpdatedAdditionalguidelinesonrationaluseofPersonalProtectiveEquipmentsettingapproachforHealthfunctionariesworkinginnonCOVID19areas.pdf>)
- ii. All healthcare workers have undergone training on Infection Prevention and Control and they are aware of common signs and symptoms, need for self-health monitoring and need for prompt reporting of such symptoms.
- iii. Provisions have been made for regular (thermal) screening of all hospital staff.
- iv. All healthcare workers managing COVID-19 cases are being provided with chemo-prophylaxis under medical supervision.
- v. Provisions have been made for prompt reporting of breach of PPE by the hospital staff and follow up action.

4. Action for Healthcare Workers

- i. Ensure that all preventive measures like frequent washing of hands/use of alcohol based hand sanitizer, respiratory etiquettes (using tissue/handkerchief while coughing or sneezing), etc. are followed at all times.
- ii. He/she shall use appropriate PPE at all times while on duty.
- iii. A buddy system* to be followed to ensure that there is no breach in infection prevention control practices.
- iv. Any breach in PPE and exposure is immediately informed to the nodal officer/HoD of the department
- v. HCWs after leaving the patient care units (wards/OPDs/ICUs) at the doctor's duty rooms/hostels/canteen or outside the HCF must follow social distancing and masking to prevent transmission to/acquiring infection from other HCWs who may be positive.
- vi. Pregnant/lactating mothers and immuno-compromised healthcare workers shall inform their medical condition to the hospital authorities for them to get posted only in non-Covid areas.

*Buddy system: Under this approach, two or more-person team is formed amongst the deployed hospital staff who share responsibilities for his/her partner's safety and well-being in the context of (i) Appropriately donning and doffing of PPEs, (ii) maintaining hand hygiene and (iii) taking requisite steps on observing breach of PPEs.

5. SOP for health work force deployment during COVID-19

5.1 SOP to be followed in case HCW reports exposure/breach of PPE

All the Healthcare workers must report every exposure to COVID-19 to the concerned nodal officer and HoD of the concerned department immediately.

The Nodal officer will get the exact details of exposure to ascertain whether the exposure constitutes a high risk or low risk exposure as described below:

- **High risk exposure:**
 - HCW or other person providing care to a COVID-19 case or lab worker handling respiratory specimens from COVID-19 cases without recommended PPE or with possible breach of PPE
 - Performed aerosol generating procedures without appropriate PPE.
 - HCWs without mask/face-shield/goggles:
 - having face to face contact with COVID-19 case within 1 metre for more than 15 minutes
 - having accidental exposure to body fluids
- **Low risk exposure:**
 - Contacts who do not meet criteria of high risk exposure

The Nodal Officer/Head of the Department will form a sub-committee to assess the level of exposure and the risk as per assessment format at Annexure I. As per their assessment:

- For doctors, nursing officers and other health workers with high risk exposure, the quarantine period shall be initially for one week only.

- Thereafter taking profile of such doctors, nursing officers and other health workers, a decision shall be taken by the Nodal Officer/Head of the Department (or his appointed Sub-committee) for further period of one week.
- After a week, they shall be tested as per ICMR testing protocol, actively monitored for development of symptoms and managed as per laid down protocol.
 - If they test positive but remain asymptomatic they will follow protocol for very mild/mild/pre-symptomatic cases as described in para 5.2.1 (a) below.
 - If they test negative and remain asymptomatic, complete 14 day quarantine and return to work.
 - Should symptoms develop, follow the guidance para 5.2.
- Low risk contacts shall continue to work. They will self-monitor their health for development of symptoms. In case symptoms develop, the guidance under para 5.2 would be followed.

5.2 SOP to be followed in case HCW reports symptoms suggestive of COVID-19

- 5.2.1** If any healthcare worker who is manifesting signs and symptoms suggestive of COVID-19, he/she will be isolated immediately and the following procedure will follow:
- a. In case of mild/very mild/pre-symptomatic case, he/she will have an option of home isolation, subject to the conditions stipulated in the revised guidelines for home isolation of very mild/pre-symptomatic COVID-19 cases (available at: <https://www.mohfw.gov.in/pdf/RevisedguidelinesforHomeIsolationofverymildpresymptomaticeCOVID19cases10May2020.pdf>). Such cases would end their home isolation as per timeline provided in the said guidelines.
 - b. In cases where home isolation is not feasible, such mild/very mild/pre-symptomatic cases will be admitted to a COVID Care Center[#].
 - c. Moderate cases that require oxygen therapy shall be managed at a Dedicated COVID Health Center[#]
 - d. Severe cases will be managed in a Dedicated COVID Hospital[#].

For cases admitted COVID Health facilities, their discharge will be governed guidelines available at: <https://www.mohfw.gov.in/pdf/ReviseddischargePolicyforCOVID19.pdf>

The details of categorization of health facilities as COVID Care center, Dedicated COVID Health Center and Dedicated COVID Hospitals along with categorization of patients (mild/moderate/severe) is available at:<https://www.mohfw.gov.in/pdf/FinalGuidanceonMangaementofCovidcasesversion2.pdf>.

- 5.2.2** Those who test negative, will be managed as in non-COVID area as per their clinical diagnosis. Their resuming work will be based on the clinical diagnosis and the medical certification by the treating doctor.
- 5.2.3** For HCWs (with low risk exposure), who continue to work and develop symptoms:
- And test positive, further management would be based on their clinical presentation and as described in para 5.2 (1) (a) above
 - Those who test negative, will return to work subject to medical certification for ailment

5.2.4 Discharge of COVID-19 positive HCWs will be in accordance with the discharge policy (available at: <https://www.mohfw.gov.in/pdf/ReviseddischargePolicyforCOVID19.pdf>).

5.3 Regular quarantine of healthcare workers after performing duty in COVID-19 areas

Quarantine of healthcare workers, other than what is stipulated above is not warranted.