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 Welfareis 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 this 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 and 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 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 executes 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 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 logistically the same need to be stored in special “Vaccine Carriers” to maintain the requisite temperature and to further prevent contamination. If 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 it 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 is 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.

<u>On the Issue of Ramping up the Immunization Drive in India</u>

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 Remedesivir 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 **a**bout 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 heath 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 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)
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VERIFICATION