

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

(Suo Motu Writ Petition (Civil) No. 03 of 2021)

APRIL 30, 2021

**[DR. DHANANJAYA Y CHANDRACHUD,  
L. NAGESWARA RAO AND S. RAVINDRA BHAT, JJ.]**

*COVID-19 Pandemic: Suo Motu cognizance of various issues relating to COVID-19 – Unprecedented humanitarian crisis following outbreak of COVID-19 pandemic – Issues as regards distribution of essential supplies and services during pandemic – Issuance of directions, recommendations and questions to the Government as regards the medical infrastructure, national policy for admission to hospitals, oxygen allocation and availability, vaccines capacity and disbursal and vaccine pricing, potentiality of compulsory licensing for vaccines and essential drugs, supply of essential drugs, black marketing and augmentation of health care workforce – Direction to Union of India to ensure that the deficit in the supply of oxygen to the Government of National Capital Territory of Delhi- GNCTD is rectified within the stipulated period – Direction to Central Government who would in collaboration with the States, prepare a buffer stock of oxygen for emergency purposes and decentralize its location – Direction to Central Government and State Governments that it would notify all Chief Secretaries/Police that any clampdown on information on social media or harassment caused to individuals seeking/delivering help on any platform would attract a coercive exercise of jurisdiction – Central Government to formulate a national policy on admissions to hospitals which would be followed by all State Governments, and till then no patient to be denied hospitalization or essential drugs in any State/UT for lack of local residential proof of that State/UT – Issuance of direction to Central Government to revisit its initiatives and protocols, including on the availability of oxygen, availability and pricing of vaccines, availability of essential drugs at affordable prices and on all the other issues – Judicial notice – Constitution of India.*

*Constitution of India: Art. 32 - Suo Motu writ petition – Unprecedented humanitarian crisis following outbreak of COVID-19 pandemic – Dialogical role of the bench – Held: Jurisdiction assumed by this*

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*Court under Art. 32 did not automatically lead to the erosion of High Court's jurisdiction under Article 226 - Jurisdiction under Article 226 is important – 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 – Jurisdiction exercised 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 approach 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 u/Arts. 21 and 14.*

*Suo Motu vs State of Gujarat Writ Petition (PIL)  
No 53 Of 2021; K.S. Puttaswamy (Privacy-9J.) vs  
Union of India (2017) 10 SCC 1: [\[2017\] 10 SCR 569](#) – referred to.*

*Sandra Fredman, "Adjudication as Accountability: A Deliberative Approach" in Nicholas Bamforth and Peter Leyland (eds), *Accountability in the Contemporary Constitution* (Oxford University Press, 2013) ; 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 ; 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; Austin Sarat and Thomas R. Kearns, *History, Memory, and the Law* (University of Michigan Press, 2009) pgs 12-13; Nicole Maurantonio, "The Politics of Memory" in Kate Kenski and Kathleen Hall Jamieson (eds), *The Oxford Handbook of Political Communication* (Oxford University Press, 2014); 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* (2020) 41:233-237, pg 233 – referred to.*

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*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, 2<sup>nd</sup> October, 2020, available at <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>; COVID-19 IP Policy Tracker (WIPO, 16 July 2020), available at <https://www.wipo.int/covid19-policy-tracker/#/covid19-policy-tracker/access>; “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-item/23-09-2020-managing-the-covid-19-infodemic-promoting-healthy-behaviours-and-mitigating-the-harm-from-misinformation-and-disinformation>>; “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>>; 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>>; 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>> – referred to.*

CIVIL ORIGINAL JURISDICTION : Suo Motu Writ Petition (Civil) No. 03 of 2021.

Tushar Mehta, SG, Ms. Aishwarya Bhati, ASG, Anil Grover, Sr. AAG, Ms. Bansuri Swaraj, Ms. Garima Prashad, Arunabh Chowdhury,

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Krishnaraj Thaker, AAGs., Mahendra Singh Singhvi, Adv. Gen., S. C. Verma, Adv. Gen. (Chhattisgarh), Purushainder Kaurav, Adv. Gen. (MP), Vivek Kolhi, Adv. Gen. (Sikkim), Amit Kumar, Adv. Gen (Meghalaya), Atul Nanda, Adv. Gen, (Punjab), Jaideep Gupta, Ms. Meenakshi Arora, Maninder Singh, Ms. Manisha Lavkumar, Dr. Abhishek Manu Singhvi, Vikas Singh, Pradeep Kumar Rai, Ms. Mahalakshmi Pavani, Brijender Chahar, Ms. Sonia Mathur, Vikas Pahwa, Rahul Mehra, Anand Grover, Ms. Indira Jaising, Amarjit Singh Chandiok, S. Niranjan Reddy, Yatin Oza, Ranjit Kumar, C.S. Vaidyanathan, Ms. Garima Prashad, Dr. Manish Singhvi, Dr. Menaka Guruswamy, Sr. Advs., Avnish Kumar Sharma, Rajat Nair, Kanu Agrawal, Amit Mahajan, Prashant Singh B, Raj Bahadur Yadav, Gurmeet Singh Makkar, A P Mayee, Amit Bhandari, Sandeep Jha, Suhaan Mukerji, Vishal Prasad, Ms. Deepeika Kalia, Nikhil Parikhshith, Abhishek Manchanda, Kapish Seth, Mrityunjai Singh, Sayandeept Pahari, M/S. Plr Chambers and Co., Arijit Prasad, Meenesh Dubey, Ms. Ritu Bhadwaj, Anupam Mishra, Ms. Nina Gupta, Ms. K.V. Bharathi Upadhyaya, Mukesh Kumar Singh, Ms. Sasmita Tripathy, Prashant Singh, Ms. Prerna Kumari, Ms. Seema Patnaha, Ms. Nandani Gupta, Rahul Kaushik, Satyakam, Gautam Narayan, Ms. Asmita Singh, Adithya Nair, Ms. Rajeshwari Hariharan, R. Sathyanarayanan, Ms. Nupur Kumar, Ms. Mantika Haryani, Ms. Astha Sharma, Nipun Saxena, Paras Nath Singh, Umang Tyagi, Ms. Serena Sharma, Prashant Kumar, Ms. Anindita Pujari, Amarjit Singh Bedi, Mahfooz Ahsan Nazki, Polanki Gowtham, Shaik Mohamad Haneef, T. Vijaya Bhaskar Reddy, Amitabh Sinha, Shrey Sharma, Purvish Jitendra Malkan, Ms. Dharita Purvish Malkan, Ms. Deepa Gorasia, Alok Kumar, Ms. Neha Ambashtha, Ms. Nandini Chhabra, Ms. Bhavna Sarkar, Manish Kumar, Balaji Srinivasan, Ms. Garima Jain, Ms. Pallavi Sengupta, Ms. Lakshmi Rao, Aishwarya Choudhary, Ms. Aakriti Priya, Mohammed Shahrukh, Prateek Yadav, Dr. Monika Gusain, Rahul Chitnis Adv., Sachin Patil, Aaditya A. Pande, Geo Joseph, M. Yogesh Kanna, Raja Rajeshwaran S., Sumeer Sodhi, Ms. Simran Agarwal, Vikram Sharma, K.V. Jagdishvaran, Mrs. G. Indira, Ms. Ruchira Gupta, Shishir Deshpande, Anurag Sharma, Abhishek Kumar Srivastava, Dr. A.P. Singh, Sadashiv, V.P. Singh, Ms. Geeta Chauhan, Ms. Richa Singh, Sharwan Kumar Goyal, Jai Gopal Saboo, Pashupati Nath Razdan, Sunny Choudhary, Pukit Agarwal, Sudhanshu Kaushesh, K.P. Jayaram, Astik Gupta, Ms. Maitrayee Jagat Joshi, A.D.N. Rao, A. Venkatesh, Rahul Mishra, Ms. Ananya

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Khandelwal, V.N. Raghupathy, Ms. Siddhesh Kotwal, Ms. Manya Hasija, Ms. Ana Upadhyay, Nirnimesh Dube, Pukhrambam Ramesh Kumar, Ms. Anupama Ngangom, Karun Sharma, Sunny Choudhary, Mrs. K. Enatoli Sema, Amit Kumar Singh, Sameer Abhyankar, Amish Tandon, Ayush Beotra, Varun Tandon, Dipin Tamang, Uddhav Khanna, Ms. Shafali Jain, Avijit Mani Tripathi, Shaurya Sahay, Chetan Joshi, G.M.Kawoosa, Ms. Taruna Ardhendumauli Prasad, Parth Awasthi, Abhimanyu Tewari, Ms. Eliza Bar, Abhinav Agrawal, Vishnu Shankar Jain, Rakesh Malhotra, Tungesh, Chirag M. Shroff, Shibashish Misra, S. Debabrata Reddy, Avnish Kumar Sharma, Jishnu M.L., Ms. Priyanka Prakash, Ms. Beena Prakash, Sandeep Kumar Jha, Karan Bharihoke, Ms. Neha Sahai Bharihoke, Siddhant Sharma, Pashupathi Nath Razdan, Pradeep Kumar Yadav, Ms. Shikha Yadav, Abhay Singh Yadav, Sanjeev Malhotra, Himanshu Chaubey, Nitin Lonkar, Ms. Sonali Suryawanshi, Himanshu Chaubey, Shibashish Misra, Haris Beeran, Mushtaq Salim, Usman Ghani Khan, Azhar Asees, Ms. Pallavi Pratap, Ms. Astha Sharma, Ms. Manju Jetley, Govind Manoharan, Ibad Mushtaq, Ms. Aishwarya Murali, Victor Das, Ms. Ambika Mathur, Mrs. Shally Bhasin, Purvish Jitendra Malkan, Ms. Raushan Tara Jaswal, Ms. Shobha Gupta, Ms. Medha Garg, Anurag Tomar, Rameshwar Prasad Goyal, S. Udaya Kumar Sagar, Ms. Sweena Nair, Ms Pragya Baghel, Kumar Anurag Singh, Ms Pallavi Langar, Devashish Bharuka, Mrs. Jaya Bharuka, Ravi Bharuka, Ms. Sarvshree, Justine George, Ms. Srishti Agarwal, Ankit Agarwal, Ms. Taniya Bansal, Manoj V George, Ranjit Philip, Ms. Palak Arora, K. Panmei, Ms. Shilpa Liza George, Shuvodeep Roy, Ms. Diksha Rai, Ms. Ninmisha Menon, Deepak A. Masih, Ms. Manreet Kaur, Ms. Kusum, R. N. Kewani, J. Sai Deepak, Guruswamy Nataraj, V. Shyamohan, Surya Prakash for M/S KMP Law, Advs. for the appearing parties. Devasish Garg, Parvesh Sahib Singh Verma, Shashank Deo Sudhi, G. Prakash, Dr. Ashwani Kumar, Viplav Sharma, Applicants-in-person.

The following Order of the Court was passed:

**ORDER**

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

**A. Introduction**

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- 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 India<sup>1</sup>, the Governments of the States and Union Territories<sup>2</sup>, 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

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<sup>1</sup> “UOI”, referred interchangeably as “Central Government”

<sup>2</sup> Collectively referred as “State Government”

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- 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, 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

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- (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;

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(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.

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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 approach<sup>3</sup> 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.

**B. Outline of the Disaster Management Act**

6. The Disaster Management Act, 2005<sup>4</sup> 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)<sup>5</sup> 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 Authority<sup>6</sup> 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.

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

<sup>4</sup> "DMA"

<sup>5</sup> "2... (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;"

<sup>6</sup> "NDMA"

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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;
- (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.

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(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

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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

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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 India<sup>7</sup> 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:

"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.,

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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 Centers<sup>8</sup>, Dedicated COVID Health Centers<sup>9</sup> and Dedicated COVID Hospitals<sup>10</sup> 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.
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

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8 "CCC"

9 "DCHC"

10 "DCH"

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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 case load, 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 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 Welfare<sup>11</sup>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 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.

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11 "MoHFW"

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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 litigation<sup>12</sup>, 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.

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

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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 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 Affairs<sup>13</sup>, 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

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supply for industrial and medical use, which is in the form of Liquid Medical Oxygen<sup>14</sup>. 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;
  - 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

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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 20 <sup>th</sup> April		
		Initial	Revised	Remarks
1	Maharashtra	1500	1500	-

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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 20 <sup>th</sup> 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	-
<b>TOTAL</b>		<b>4880</b>	<b>5619</b>	

(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;

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

SI 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	1389.19
2	Goa	No Bulk Manufacturing Plant	11	11	
3	Gujarat	847.00	1000	975	904.20
4	Dadra & Nagar Haveli	No Bulk Manufacturing Plant	20	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	180.38
11	Chandigarh		20	40	
12	Tamil Nadu	366.00	280	220	396.48

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

(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;

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(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 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 India<sup>15</sup> 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;

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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 Absorption<sup>16</sup> 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 <sup>17</sup>	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 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

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.”

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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 filled 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

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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 Delhi<sup>18</sup>. 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 careunit.

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28. Opposing his submission, the Solicitor General and Ms Dawrastated 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) 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.

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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

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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/containersto 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
- (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.

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**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-19<sup>19</sup> 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 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**

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**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 GoI 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

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(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 nation-wide 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

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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

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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)**

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 manufacturers 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

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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 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

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(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 India<sup>20</sup> 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:

- (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 correlation 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.

**SUPREME COURT REPORTS****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 provisioning of affordable medical products to patients<sup>21</sup>. 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, 1970<sup>22</sup>, 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”

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44. The utilization of these flexibilities has also been detailed in the Trade Related Aspects of Intellectual Property Rights Agreement<sup>23</sup>. 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 objectives<sup>24</sup>. 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 case<sup>25</sup>, the aforesaid caveat does not apply when the compulsory license grant is for national emergency, extreme urgency or public non-commercial use<sup>26</sup>.
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 medicines<sup>27</sup>. 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 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 licenses<sup>28</sup>.

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.

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

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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 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;

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- (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 Authority<sup>29</sup> 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 Ingredients<sup>30</sup> 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;
- (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

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29 “NPPA”

30 “API”

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(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 itiluzumab, 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 Pharmaceuticals<sup>31</sup>, NPPA and DCGI had reviewed the production and supply of other drugs such as Favipiravir, Enoxaparin, Ivermectin, Methylprednisolone,

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31 "DoP"

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Paracetamol and Hydroxy-chloroquine. 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 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 19<sup>32</sup> 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

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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.”

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is available even to the most marginalized sections of the society. The Government can even monitor the prices of the drugs under paragraph 20<sup>33</sup> of the Drugs Price Control Order, 2013 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 25 April 2021 by DoP, NPPA and DGCI with the manufacturers to review stock position, availability and production plans. The Central

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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 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."

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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 provisions<sup>34</sup>. 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.

### 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.

<sup>34</sup> Paragraph 3 and 19 of the Drugs Price Control Order, 2013

**SUPREME COURT REPORTS****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 Organisation<sup>35</sup>, 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 disinformation<sup>36</sup>. 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 media<sup>37</sup>.
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

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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/23-09-2020-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>>

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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 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<sup>38</sup>, 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 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

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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

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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*”<sup>39</sup>, is important for the creation of knowledge of the problems plaguing us today, so they may be passed on across time<sup>40</sup>. 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 who died in World War I), has been almost entirely erased from our collective public memory<sup>41</sup>. Therefore, the widespread sharing of information by individuals living through

39 Theodore O. Prose,

‘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

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>>

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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 terms<sup>42</sup>:

“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)**

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.

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

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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 it<sup>43</sup>. 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*”<sup>44</sup>. 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 proven scientific evidence and best practices and to serve to community at large*”<sup>45</sup>, 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

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>>

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

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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 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.

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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;

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- (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.*

*Headnotes prepared by: Nidhi Jain*

*Result of the case:  
Directions issued.*