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Distribution of Essential Supplies and Services during Pandemic

TUSHAR SRIVASTAVA¹

ABSTRACT

The global COVID-19 pandemic came up with its second wave which has been deadlier and much more horrifying globally, especially in India. The count of positive cases has elevated to record peaks exceeding 3 lakh per day and the number of deaths per day over 3000. Hospitals are running out of beds and low on oxygen. There is significant shortage of essential drugs. There is increased pressure on all fronts to minimize the effects of second wave by accelerating vaccination. In this context, the court took suo motu cognizance of the situation to curb the effect of the deadly wave and save the population from the ongoing pandemic. The order inculcates the directions to the Central and State/UT governments regarding the management of vaccination drives, supply of essential drugs and identifying vulnerable age groups in accordance with the changing nature of pandemic.

I. INTRODUCTION

CJI Bobde's bench took suo moto cognizance of the situation on April 22. The case was first heard on April 23. CJI Bobde retired on the same day. Further the case was listed to Justice D Y Chandrachud on 27 April, 2021.

The Supreme Court, on April 27, Tuesday, appointed senior advocates Jaideep Gupta and Meenakshi Arora as *amici curiae* to assist the Court. Justices DY Chandrachud, L Nageshwara Rao and Ravindra Bhat bench passed an order to this effect a few days after senior advocate Harish Salve recused himself from the position. The tentative framework following issues is further taken into consideration by the court:

- Demand for oxygen and the steps taken towards monitoring its supply.
- Allocation of oxygen to states/UTs and frequent communication regarding the needs.
- The vacant beds in hospitals and treatment centres.
- Norms for admitting patients to hospitals.

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- Steps to be taken towards availability of essential drugs and controlling prices and hoarding.
- Frequent communication of requirement of drugs from Districts and States.
- Projected number of vaccines needed and steps to procuring them in order to fulfil the second dose dues.
- The procedure of allocating vaccines to States and the rationale for pricing of vaccines (considering differential pricing for the States/UTs).

Mr Tushar Mehta, the Solicitor General relied upon the affidavit of UoI dated May 9, 2021 and made the following points in relation to vaccination:

Entire nation shall be vaccinated by December 2021 and for the supply of vaccines the Central Government is actively participating in business with some foreign agencies. There will be no notable competition between States/UTs as a consequence of the updated vaccination policy. 45 years and above aged people does not have to book online slot for vaccination as they can get vaccinated through on-site registration.

The amici curiae have also raised the following issues relating to vaccine distribution, different pricing and future preparedness:

- Foreign manufacturing companies only deal with federal governments of nations.
- In the UIP², central government procures needed vaccines and is responsible for distribution in States/UTs. Liberalized vaccination policy replaced the UIP on May 1st in the nation.
- This policy makes UoI, the monopolistic buyer to act for the entire population of the country giving manufacturers the chance to implement different procurement prices for vaccinating different age groups for center, states/UTs and private hospitals. This directly affects people from poor socio-economic background.
- Alternatively, all states/UTs have agreed to vaccinate people free of cost. Thus, the final outcome is not impacted by the differential pricing of Liberalized Vaccination Policy. To this the Amici further raised concerns that:
 - The policy statement to vaccinate their citizens free must be confirmed by the State/UTs on affidavit before the court. This will give enforcement right to the citizens to avail free vaccination.

² Universal Immunization program

- It cannot be stated conclusively that all states/UTs have agreed to provide free vaccination as some of them have advanced submissions for universal vaccination by central government.
- The outcome of Liberalized vaccination policy is that UoI can purchase the vaccine at Rs 150 per dose whereas states/UTs at Rs 300-400 per dose. Had central government been responsible, people would've vaccinated at much lower price.
- The Policy conflicts with the constitutional balance of responsibilities between the Centre and States/UTs.
- The said policy has affixed a quota of 50:25:25 for 18- 44 age group. 25% is secured by both States/UTs and private hospitals, which is not at all in proportion. For effective vaccination by state government, the quota of private hospitals must be reduced.
- The CoWIN portal does not prioritize the citizens, it's merely on the basis of first-cum-first-serve.
- It is claimed by UoI that 100 crore people will be vaccinated by the end of 2021, however it is unsure, how the objective would be achieved. The population aged between 18-44 years is around 59 crores and to vaccinate them with two doses each, over 120 crore doses would be needed. For the production of these many doses, it will take over 12 months for everyone to be inoculated.
- There should be medical guidance in the production and quality of masks. The government may also form guidelines and protocol for cremation of the dead.

II. NATIONAL VACCINATION POLICY

In phase 1, from January 16 2021, Healthcare workers and Frontline Workers (from February 2) were vaccinated. In phase 2, people over 60 years of age and 45 years of age with certain co-morbidities (from 1 March 2021) and all persons over 45 years of age (starting from 1 April 2021) were eligible for vaccination. From phase 2, the eligible beneficiaries could register and book appointment on CoWIN and other apps like Aarogya Setu.

Elements of National Vaccination Policy:

- Vaccine manufacturers should supply 50% of doses to central government and rest can be procured by states/UTs and private hospitals
- Price set by private hospitals for vaccination would be monitored.
- Free vaccination shall be provided to eligible population at centers which receive the doses through UoI.

- CoWIN platform shall manage the vaccination process including price and stock of vaccines. State-wise quota of vaccine distribution would be decided in advance by the UoI.

III. SEPARATION OF POWER

The scope of jurisdiction of this court in the exercise of Judicial Review power over the management of the Covid-19 Pandemic in India is clarified in the order. The Union of India highlighted a few concerns listed below in its affidavit dated May 9, 2021:

The Government needs discretion to formulate policy for the executive is battling the unprecedented pandemic crisis. The current steps are taken with the view of minimising the effect of the second wave. These steps might not be as good in a long-run as they are in the short-term, so they need to be appreciated for now. Power of judicial review is permissible over executive policies only on account of manifest arbitrariness. Any ardent intervention of judiciary without expert advice or administrative experience may hinder executive from making innovative solutions.

It is a hackneyed saying that separation of power is a part of basic structure of constitution. Policy making lies in the domain of executive. The Judiciary is not competent enough to assume the role of the executive. However, our constitution does not visualise courts as ‘silent spectators’ while executive policies infringe constitutional rights of citizens. Hence, separation of powers does prohibit Courts from conducting Judicial Review of such policies.

It was made clear in the order dated April 30, 2021, that the court appreciates the dynamic nature of measures in the context of public health emergency in the country. Wider margin has been given to the executive in enacting measures, which in ordinary course may have violated the liberty of individuals, but are now necessary to curb the pandemic. The Apex Court of the United States in case *Jacobson vs Massachusetts*³, considered a constitutional liberty challenge to a mandatory vaccination law that was introduced to combat the smallpox epidemic in 1905.

In battling with the second wave of Covid-19, the intention of the court is not to doubt the wisdom of executive in choosing between effective policy measures. Nonetheless, the court has the jurisdiction to decide whether the chosen policy measure is in parallel to the standards of reasonableness and protects the right to life of every person. The court shall further conduct deliberations for evaluation of existing policies to assess whether they survive the constitutional scrutiny.

³ 197 U.S. 11 (1905)

IV. ISSUES WITH THE LIBERALIZED VACCINATION POLICY

Vaccine procurement and distribution to different categories of population

The Union of India was directed to clarify the terms of Vaccine procurement and distribution in the coming months. UoI was also directed to inform about the projected number of vaccination and the efforts of production of that number.

UoI, in its affidavit dated May 9, 2021 made the following submissions:

- The vaccination policy adopted in phase 1 and 2 was formulated as a procedure of prioritization. In phase 1, Healthcare workers (from January 16) and Frontline Workers (from February 16) were vaccinated. In phase 2, people over 60 years of age and 45 years of age with certain co-morbidities (from 1 March 2021) and all persons over 45 years of age (starting from 1 April 2021) were eligible for vaccination.
- The Liberalized Vaccination Policy was implemented effective from 1 May 2021. The policy aims to achieve greater efficiency and reachability. The priority of the UoI remains vaccinating persons aged 45 years and above without charging any cost. Simultaneously, vaccinations for persons between 18-44 years of age has been introduced.
- To eliminate inconsistency in bargaining powers, the Central Government has determined the expected eligible population of each state and states shall procure only that number of vaccines. The Centre shall further notify about the number of distributions to each state, every two weeks. NEGVAC⁴ has produced 6.6 crore doses in the initial phases. ‘Mission Covid Suraksha’ is providing support to other candidates under clinical development. Manufacturing capacity is being increased massively in coming months.

The major issues are: (i) vaccine distribution between different age groups; (ii) vaccine procurement process; and (iii) the augmentation of the vaccine availability in India. The affidavit clarifies the prioritization of age groups. The prioritization is based on global experience and in India during first and second waves considering the more vulnerable age groups. The changing nature of pandemic required vaccination at rapid pace.

Foreign manufacturers prefer to negotiate with federal governments of the country rather than States/UTs. The amici curiae have raised concerns that there is a lack of clarification relating to the intervention of UoI in the distribution process. It is difficult to understand the pro rata allocation.

Mr. Tushar Mehta has stated that he is in position to address the concerns of court and that the

⁴ National Expert Group on Vaccine Administration for COVID-19

UoI aims to vaccinate 100 crore people by December, 2021.

The Union of India is directed to review of its policy and provide following clarifications:

It needs to provide a roadmap of projected availability of vaccines by December 31, 2021. Preparation of medical infrastructure for children amidst third wave. The clarity in the mechanism of redistribution if in any state/UT, either of the two wings do not pick the 25:25 quota.

V. EFFECTS OF VACCINATION BY PRIVATE HOSPITALS UNDER THE LIBERALIZED VACCINATION POLICY

- The total vaccines produced will be divided in a ratio of 50:25:25 between the Central Government, State/UT Governments and private hospitals under Liberalized Vaccination Policy.
- As a result of Liberalized Vaccination Policy 50% of any state's population is expected to pay for vaccine doses.
- Private hospitals may sell the doses at much higher prices if not regulated stringently. They might not sell all the vaccines through CoWIN to get better deal to other private organisations. These hospitals are present in big urban cities which will result in less quantity of vaccines in rural areas.
- Though the private hospitals lessen the burden of the government, following clarification is sought from the UoI for the issue of privatizing 50% of all vaccines:
 - The manner of monitoring the disbursement of vaccines to the private hospitals, whether private hospitals are liable to disburse vaccines, the mechanism to determine if private players are actually administering the lifted quota in that state/UT.
 - The manner in which state and centre shall ensure effective and equal distribution of vaccines.
 - The intervention nature with respect to the final price charged by the private hospitals.

VI. IMPACT OF DIFFERENTIAL PRICING

The UoI, in its affidavit dated May 9, 2021, stated that Differential Pricing was introduced in order to inculcate competitive market and invite more manufacturers of vaccines to ensure rapid vaccination. It is mandatory for the manufacturers to transparently declare the price so that the States/UTs and private hospitals may procure the vaccines. All persons of all ages shall be vaccinated free of cost.

The Liberalized Vaccination Policy enables States/UTs to procure 50% of the CDL⁵ approved doses. The UoI has pre-fixed the quantity and price, the only room for negotiation with the two vaccine manufacturers. Rs 35000 had been earmarked for procuring vaccines in the Union Budget for Financial Year 2021-22. The clarity has been sought from UoI about the spending of the funds.

The Central Government stated that the final outcome would stay unaffected by the Liberalized Vaccination Policy since free vaccination has been promised by the States/UTs. Nevertheless, it is reiterated that the UoI should consider utilizing its position as the monopolistic buyer in the market and pass down the benefit to all persons.

If the unique monopolistic buyer position of UoI is the only reason for it to receive vaccines at a much lower rate from manufacturers, it is important for us to examine the rationality of the existing Liberalized Vaccination Policy against Article 14⁶ of the Constitution, since it could place severe burdens, particularly on States/UTs suffering from financial distress.

VII. BASIS OF DIFFERENTIAL PRICING

The UoI's stance is sought to drive down the costs and elevate the manufacturing of Covishield and Covaxin vaccines. The following justifications has been adduced in its affidavit dated May 9, 2021:

- Both the manufacturers (SII and BBIL) have taken financial risks to manufacture the vaccines. ICMR⁷ would receive 5% royalty on net sales of covaxin of which phase 3 trials have been funded by the ICMR in the tune of Rs 35 crore.
- Covishield is manufactured by SII. The Central Government has directly transferred Rs 11 crores to 14 clinical trials sites for conducting phase 3 trials of over 1600 participants.

The court has sought the clarifications from the UoI. Comparison between the prices of vaccines being made available in India, to their prices internationally. Whether ICMR/BBIL formally invited contracts for voluntary licensing and if so, whether they have they received viable offers. The manner in which the UoI is independently trying to assist manufacturers for developing BSL3 labs which are essential for Covaxin production.

VIII. VACCINE LOGISTICS & DIGITAL DIVIDE

The court sought certain clarifications from UoI regarding the management of storage and the

⁵ Clinical Diagnostic Laboratory

⁶ Equality before law

⁷ Indian Council of Medical Research

logistical burden for vaccinating persons aged between 18-44 years, along with persons aged over 45 years between central and state governments. Further it seeks clarity about the steps taken in order to improve cold storage facility.

The UoI made submissions relating to CoWIN portal. 4 persons could register using one mobile number. NGOs, CSCs⁸, are there to help people who are not digitally advanced. Identity proofs are required for determining the age and tracking who is due for second dose.

Reports from Telecom Regulatory Authority and National Statistics Office stated that the majority of population is unaware of the usage of computer and number of wireless users is very less in rural areas. In states like Uttar Pradesh and Bihar, the tele density is below 75%. According to annual report of CSC, over 13000 Gram Panchayats do not have CSCs.

Hence, there exists a digital divide in India, particularly between the rural and urban areas. A vaccination policy exclusively relying on a digital portal for vaccinating a significant population of a country like India between the ages of 18-44 years would be unable to meet its target of universal immunization owing to such a digital divide.

In this regard, following clarifications were sought from the UoI:

- NGOs alone are not competent to book vaccination slots when even digitally sound population are finding it hard to book slots.
- The accessibility of the portal to the disabled/physically challenged must be clarified.
- CoWIN and other IT applications like Aarogya Setu should be made available in regional languages for convenience and better usage by the marginalized sections of the society.

There are some issues in the CoWIN application that are to be addressed to make it accessible for visually challenged and people with other disabilities such as unavailability of audio or text captcha, a drop-down list to address the seven filters related to vaccine and the person getting vaccinated, following accessibility protocols and providing enough time before automatically logging off. Keyboard navigation is absent.

IX. CONCLUSION

UoI is finally directed to make submissions regarding the number of vaccinations done with details of first or both doses, the roadmap of vaccinating remaining population, the complete data of purchase of all COVID-19 vaccines made by the Central Government. The steps being taken by the Central Government to ensure drug availability for mucormycosis⁹ to be made

⁸ Common Service Centres

⁹ Mucormycosis or black fungus is a complication caused by fungal infection.

clear in the submission. States/UTs must clarify their position in providing free vaccination. The said affidavits must be filed within two weeks.
