Courts as an Arena for Scientific Vaccination

Anmol Gulecha, LL.M
PhD Candidate
Tilburg University
The Netherlands.

INTRODUCTION

The Office of the Commissioner of Human Rights (OHCHR) recognized COVID-19 vaccination as an 'important scientific achievement.'[1] These vaccines play an essential part in the road to recovery from COVID-19, but if countries fail to rationally prioritize vaccination amongst its most vulnerable population,[2] the road to recovery and the right to health of all persons will be 'undermined.'[3] This note finds, despite World Health Organization's ('WHO') scientific advice, countries fail to issue scientifically rational policies. In such situations, the note concludes certain Constitutional Courts – specifically the Supreme Court of India ('Indian Supreme Court') within the Indian context can initiate *suo motu* litigation against the government[4] and compel the government to correct the policy.[5]

The WHO's advice, which will be analyzed in the next section, held that vaccine prioritization though essential must consider vulnerabilities.[6] Subsequent advice also urged, primary series doses must first be offered to higher priority-use groups comprising of health care workers, elders, and immunocompromised people.[7] However, for example, Kenya prioritized vaccination for diplomats over elderly and healthcare workers.[8] Similarly, Indonesia decided to vaccinate 'more productive

[1] Human Rights Council, 'Human rights implications of the lack of affordable, timely, equitable and universal access and distribution of coronavirus disease (COVID-19) vaccines and the deepening inequalities between States: Report of the United Nations High Commissioner for Human Rights' 1st February 2022 A/HRC/49/35
[2] Ibid
[3] Ibid
[4] The Court on its own motion initiates a case without the requirement of a formal petition being presented to Court.
[5] Pranay Maladi, 'Responding to Executive Under and Overreach: Indian Supreme Court and Constitutional Adjudication in the Pandemic' (2021) 10 Indian Journal of Constitutional Law 1.
[6] World Health Organsation, 'Strategic Action Group of Experts, values framework for the allocation and prioritization of COVID-19 vaccination issued on Sep 2020' (2020) WHO/2019-nCoV/SAGE_Framework/Allocation_and_prioritization
[7] World Health Organization 'SAGE roadmap for prioritizing uses of COVID-19 vaccines: an approach to optimize the global impact of COVID-19 vaccines, based on public health goals, global and national equity, and vaccine access and coverage scenarios' first issued 20 October 2020, updated: 13 November 2020, updated: 16 July 2021, latest update: 21 January 2022 available at WHO-2019-nCoV-Vaccines-SAGE-Prioritization-2022.1-eng.pdf (WHO SAGE Roadmap)
[8] David Lewis and Maggie Fick, 'Kenyan COVID vaccine offer to diplomats draws local doctors' ire' *Reuters* (Nairobi, 20 March 2021)

members of society' from 18 to 59 years before vaccinating the elderly (above 60 years).[9] Likewise, India adopted two different vaccination policies for healthcare workers, people above 45 years and people between 18 to 44 years (immunocompromised persons between 18 years to 44 years fell with the latter category as well). Experts criticized the Indian vaccination policy for promoting inefficiency and inequality.[10] While the Kenyan and Indonesian policies were not challenged before courts, the Indian Supreme Court's *suo motu* challenge to the government's policy could show the OHCHR, that courts can play an important role in the road to recovery.

RATIONAL VACCINE CLASSIFICATION

In September 2020, the WHO's Strategic Advisory Group of Experts on Immunization ('SAGE') issued a Framework for the allocation and prioritization of COVID-19 vaccination (the Framework). The Framework provides six core principles that should guide '[…] prioritizing groups for vaccination within each country.'[11] Out of the six principles, Principle 4 suggests to 'ensure that vaccine *prioritization within countries takes into account the vulnerabilities, risks and needs* of groups who, because of underlying societal, geographic or biomedical factors, are at risk of experiencing greater burdens from the COVID-19 pandemic;' (emphasis added)

Followed by the Framework, the SAGE issued a 'Roadmap for Prioritizing Use of COVID-19 Vaccines: An approach to optimize the global impact of COVID-19 vaccines, based on public health goals, global and national equity, and vaccine access and coverage scenarios in October 2020 which was updated on 21st January 2022 (Roadmap)'.[12] This Roadmap suggests 'Primary series doses should not be offered to lower priority-use groups without first being offered to higher priority use groups unless there is adequate justification to do so.'[13] Second, Immunocompromised persons are included in the 'Highest priority use' for vaccination, this is irrespective of age of the person. 'Similarly, as regards to equity, this Roadmap also identifies, for special consideration, adults from disadvantaged communities experiencing higher rates of poor health and inadequate health care, as well as higher risks of COVID-19.' Finally, the roadmap held overly complicated

[9] Bimandra Djaafara, 'Commentary: Indonesia's questionable decision on vaccinating only those aged 18 to 59' *CAN* (London, 3 February 2021)
[10] R Ramakumar, 'India's Covid Vaccine Policy Is Bound to Promote Inefficiency, Inequality'. *The Print,* (7 May 2021) available at https://theprint.in/opinion/indias-covid-vaccine-policy-is-bound-to-promote-inefficiency-inequality/653836/.
[11] WHO SAGE Framework
[12] WHO SAGE Roadmap
[13] WHO SAGE Roadmap

or prescriptive prioritization schema are difficult to implement and thus have limited use. Likewise the OHCHR advised, 'Decisions on priority consideration for vaccinations should be made on the *basis of appropriate criteria reflecting the best available scientific evidence and in line with human rights standards and norms*, while avoiding exclusionary approaches that reinforce existing lines of inequality.'[14] (emphasis added)

Countries around the world, according to the Framework, the Roadmap, and OHCHR's advice put in place their own vaccination policies on a priority basis. For example, in Singapore, senior citizens were vaccinated first, followed by the remaining.[15] In the Netherlands the healthcare works were vaccinated first, followed by the elderly, etc.[16] On the contrary, the Central government in India issued an 'overly complicated' prioritization policy which seemed 'irrational', 'exclusionary', 'reinforced existing lines of inequality' and contrary to human rights approach.

INDIA'S VACCINATION POLICY AND ITS EFFECTS

India began to vaccinate its population against COVID-19 on 16th January 2021.[17] The vaccination drive was initiated in three phases - Phase I, II, and III - as set out in the guidelines for 'Implementation of National COVID Vaccination Program'.[18] Phase I and II targeted the health case workers and population more than 45 years. The strategy followed a single tier pricing system where 100% of the vaccine doses were procured by the central government from the manufactures and provided free of cost to the respective state governments to vaccinate their population.[19]

The central government of India changed the policy in Phase III which was covered by the 'Liberalised Pricing and Accelerated National Covid-19 Vaccination Strategy' ('the vaccination policy').[20] Phase III targeted the population in the age group of 18 to 44 years. The vaccination policy followed a three-tier pricing system determined by the central government, the state

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[14] Human Rights Council
[15] Hariz Baharudin, 'Seniors across Singapore to start getting vaccinated against Covid-19 from Feb 22: PM Lee', *The Straits Time* (Singapore, 12 February 2021)
[16] Piroschka van de Wouw, 'Nurse first in Netherlands to get COVID-19 vaccination' *Reuters* (Netherlands, 6 January 2021)
[17] ('Coronavirus Vaccine')
[18] Government of India, Liberalised Pricing and Accelerated National Covid-19 Vaccination Strategy issued on 21 April 2021.
[19] Sudhan Rackimuthy et al, 'COVID-19 vaccination strategies and policies in India: The need for further re-evaluation is a pressing priority' (2022) 37(3) International Journal Health Planning Management 1847 at 1848.
[20] Government of India, Liberalised Pricing and Accelerated National Covid-19 Vaccination Strategy issued on 21 April 2021.

government, and the private hospitals with the ration as 50:25:25.[21] In this policy 50% of the vaccine doses were procured by the central government and provided free of cost to the state governments for vaccination. Then vaccine manufactures can sell a maximum of 25% of their monthly vaccine supply directly to private hospitals and the remaining 25% directly to state governments.

The vaccination policy hindered India's vaccination drive and in turn recovery from COVID-19. First it placed a financial burden on the population between 18 to 44 years, who also face similar financial inequalities like the target group in Phase I and II. Second, immunocompromised persons between 18 to 44 years fell in Phase III, which meant they did not receive priority vaccination. Third, while the vaccination policy allowed the state government to directly buy vaccines from the vaccine manufactures, the manufactures were not willing to negotiate with the state government. For example, in New Delhi, the National capital, the government was unable to negotiate with the vaccine manufacturers and ultimately ran out of vaccines.[22] Despite the adverse fallouts from the vaccination policy, the central government of India was unwilling to revise the policy. That prompted the Indian Supreme Court to initiate a *suo motu* challenge to the vaccination policy.

THE SUPREME COURT PAVES THE ROAD TO RECOVERY

During the second wave of COVID infections but before Phase III of the vaccination drive was due to come into effect, the India Supreme Court initiated a *suo motu* public interest case *In Re: Distribution of Essential Supplies and Services during the Pandemic (COVID case)*.[23] While the Court suo motu COVID case to put in place a universal and proper treatment plan for COVID,[24] the Court issued notice to the central government to place before the Court a national plan for production, supply, and distribution of vaccines.[25]

During the next hearing, the central government apprised the India Supreme Court on the vaccination policy, as described in the previous section. In response to the queries of the Court as

[21] Sudhan Rackimuthy et al, 'COVID-19 vaccination strategies and policies in India: The need for further re-evaluation is a pressing priority' (2022) 37(3) International Journal Health Planning Management 1847 at 1848.
[22] Writer, 'Pfizer says it will supply Covid vaccine only to central govt, not states' *Business Standard* (India, 24 May 2021); Writer, 'Moderna, Pfizer said they'll deal only with Centre, not states: Delhi govt' *Hindustan Times* (24 May 2021)
[23] Suo motu Writ Petition (Civil) 3 of 2021 (suo motu COVID case). The case was initiate on 22 April 2021.
[24] See Supreme Court order dated 22nd April 2021 in Suo motu Writ Petition (C) 3 of 2021
[25] Ibid

to how the supplies of vaccine will be allocated between state governments, if the state governments themselves were to negotiate with the vaccine producer, the central government replied,

> '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.[26]

Prima facie, the Court expressed practical reservations on the vaccination policy. The Court felt a separate procurement policy, for persons between 18 to 44 years, which leaves the state government to negotiate supply schedules, delivery points, etc may led to chaos and uncertainty. In addition, the Court felt with only two vaccine suppliers in India, each state government may not achieve the desired supply. Only those state government with higher bargaining power may get access to vaccines – thereby 'undermining the right to health for all persons.' The Court made this a central issue because 'vaccination appears to be one of the most important strategies to combat further spread of the pandemic and would also provide a measure of security and assure the people about their health and well-being.'[27] However the Court did not strike down the policy and gave the central government another chance to clarify the vaccination policy.

The central government by means of affidavit dated 9th May 2021 attempted to clarify the vaccination policy, once again. Based on the affidavit the Court appointed two amici curiae,[28] who presented three broad issues of concerns over the vaccination policy – vaccine distribution between different age groups, vaccine procurement process, and the augmentation of the vaccine availability in India.[29]

Based on these submissions the Court observed while the central government prioritized vaccination in Phase I and II due to higher risk of infection, the government failed to prioritize

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[26] See Supreme Court order dated 31st April 2021 in Suo motu Writ Petition 3 of 2021
[27] ibid
[28] Amici curiae or just Amicus curiae is a neutral third party appointed by the Court to assist the Court in the case. This is known as a 'friend of the Court.'
[29] See Supreme Court order dated 31 May 2021 in Suo motu Writ Petition 3 of 2021

persons with comorbidities and other diseases, persons with disabilities, or any other vulnerable groups in Phase III, which violated the right to health.[30] The Court goes on to point out that 'persons between 18-44 years of age have not only been infected by COVID-19, but have also suffered from severe effects of the infection, including prolonged hospitalization and, in unfortunate cases, death.'[31] Finally, the Court held, 'due to the importance of vaccinating individuals in the 18-44 age group, the policy of the central government for conducting free vaccination in Phase I and II and replacing it with paid vaccination by the State/UT Governments and private hospitals for the persons between 18-44 years, in Phase III, is prima facie, arbitrary and irrational.'[32] The Court's observation align with WHO's advice as mentioned in section 2.

Next, when the amici made the Court aware of unsuccessful attempts made by state governments to procure vaccine from the vaccine manufactures because vaccine foreign manufactures were not inclined to negotiate with individual state governments, the Court held, 'We find that the submissions urged by the Amici are extremely pertinent and have indicated that in practice, [the vaccination policy] may not be able to yield the desired results of spurring competitive prices and higher quantities of vaccines.'[33]

The Court orders and observation prompted the central government to change the vaccination procurement and distribution policy.[34] In June 2021, the Central government issues Revised Guidelines for implementation of National COVID Vaccination Program (Revised guidelines).[35] The Revised guideline follows a two-tier vaccine pricing system, first 75% of the vaccine doses were procured by the central government and provided free of cost to state governments to

[30] See Supreme Court order dated 31 May 2021 in Suo motu Writ Petition 3 of 2021; Mehal Jain "Article 1 Says Bharat Shall Be A Union Of States": Supreme Court To Centre -Read Full Courtroom Exchange In Suo Motu Covid Case. 31 May 2021.
[31] See Supreme Court order dated 31 May 2021 in Suo motu Writ Petition 3 of 2021
[32] ibid
[33] ibid
[34] (Roy; Ginsburg and Versteeg) Debayan Roy, 'Bounded Deliberative Approach: Justice DY Chandrachud Explains How Supreme Court Order Prompted Union Govt to Change COVID Vaccination Policy' *Bar and Bench - Indian Legal News*, (13 July 2021); Tom Ginsburg and Mila Versteeg, 'The Bound Executive: Emergency Powers during the Pandemic' (2021) 19(5) International Journal of Constitutional Law 1498.
[35] Government of India, Revised Guidelines for implementation of National COVID Vaccination Program with effect from 21st June 2021

vaccinate all individuals above 18 years of age.[36] Second, the vaccine manufactures can sell only maximum of 25% of their monthly vaccine supply to private hospitals in India.

CONCLUSION

By seeking scientific clarifications through a dialogic approach, the Indian Supreme Court was able to review the vaccination policy. Based upon the data from the central government in its affidavit and the data from the amici, the Court could challenge the rationality and scientific validity of the policy. While courts are not scientific experts, but scientific data could equip courts deal with scientific matters. Therefore courts such as the Indian Supreme Court, with strong powers of judicial review can use scientific data through a dialogic method to challenge bad policy and paved the road towards recovery.

[36] Government of India, Revised Guidelines for implementation of National COVID Vaccination Program with effect from 21st June 2021