BEFORE THE HON'BLE HIGH COURT OF KERALA AT ERNAKULAM

W.P.(Civil) No. of 2021

(Special Original Jurisdiction)

Petitioner:-

Mathew Nevin Thomas,

Vs.

Respondents:-

1. Union of India,
   represented by the Secretary to Government,
   Ministry of Health & Family Welfare,
   Room Nos. 514-B/A, Nirman Bhawan, New Delhi – 110011

2. Ministry of Home Affairs,
   represented by the Secretary to Government,
   North Block, New Delhi - 110001

3. Indian Council of Medical Research
   Represented by its Director General,
   Ansari Nagar, New Delhi – 110029

4. Drug Controller General of India
   Central Drugs Standard Control Organization
   Directorate General of Health Services,
   Ministry of Health & Family Welfare,
   Government of India
   FDA Bhawan, Kotla Road, New Delhi – 110002

5. Controller General of Patents,
   Boudhik Sampada Bhavan,
   Antop Hill, S.M. Road, Mumbai – 400037

6. State of Kerala,
   Represented by the Chief Secretary to the Government,
   Government Secretariat,

Thiruvananthapuram – 695001

7. Serum Institute of India Private Limited,
Represented by its Managing Director,
212/2, Hadapsar, Off Soli Poonawalla Road,
Pune, Maharashtra – 411028.

8. Bharat Biotech International Limited,
Represented by its Managing Director
Genome Valley Shameerpet, Hyderabad,
Telangana – 500 078.

9. Department of Pharmaceuticals,
Represented by its Secretary,
Shastri Bhawan, New Delhi - 110001

10. National Pharmaceutical Pricing Authority,
3rd/5th Floor, YMCA Cultural Center Building 1,
Jai Singh Road,
New Delhi, India – 110001

11. National Disaster Management Authority,
NMDA Bhavan, Safdarjung Enclave,
New Delhi-110029,
Represented by its Member Secretary.

12. Kerala State Disaster Management Authority,
Vikas Bhavan PO, Observatory Hills,
Opposite Kanakakkunnu Palace,
Thiruvananthapuram-695033,
Represented by its Member Secretary.

The Address for service of notice and process to the petitioner is that of his counsel **M/s Santhosh Mathew, Arun Thomas, Jennis Stephen, Vijay V. Paul, Karthika Maria, Veena Raveendran, Anil Sebastian Pulickel, Divya Sara George, Jaisy Elza Joe, Aby Benny Areekkal, Leah Rachel Ninan, Nanda Sanal, Karthik Rajagopal, Sanita Sabu Varghese, and Manasa Benny George, M/s. Ninan & Mathew Advocates.**

The address for service of notice on the respondents is as stated above.

MEMORANDUM OF WRIT PETITION FILED UNDER ARTICLE 226 OF THE CONSTITUTION OF INDIA

STATEMENT OF FACTS

1. The Petitioner herein is a lawyer practicing before this Honourable Court, aged about 25 years, who is a public-spirited citizen of India. The Petitioner is extremely concerned by the ongoing Coronavirus disease 2019 (hereinafter, "COVID-19") pandemic, with over 3 lakh Indians being reported as having been newly infected daily and over 25 lakh active cases as of the date of filing of this petition, which at present also includes the Petitioner's grandparents and other close relatives. COVID-19 is also claiming people's lives at an alarming rate, including that of the late Prof. Varadaraja Shivaraya Mallar, the Petitioner's former Constitutional Law teacher at the National Law School of India University, Bengaluru. The petitioner herein, whose constitutional aspirations were framed by the teachings of Prof. Mallar, is approaching this Hon'ble Court seeking affirmation that the constitutional principles of right to life, equality and dignity, taught to generations of lawyers by teachers like Prof. Mallar, continue to operate during difficult times such as these. Specifically, the petitioner herein is preferring this Writ Petition in public interest, seeking *inter alia* to challenge the 1st Respondent's Liberalised Pricing and Accelerated National Covid-19 Vaccination Strategy (hereinafter, the "Liberalised Strategy"), made available on its website on 21.04.2021, a copy of which is produced herewith and marked as **Exhibit P1**, which

has overlooked well-settled constitutional principles as well as the fundamental rights of Indian citizens. It is submitted that the Petitioner has no private or political interest in the cause he is espousing by way of this Public Interest Litigation and the Petitioner has not filed any Public Interest Litigation before any Court till date.

2. The COVID-19 pandemic reached India's doorstep with the first diagnosed case of the virus being reported in Kerala on 01.03.2020. It then went on to spread rapidly within the country, due to which the 1st Respondent executed measures nationwide through its various arms, including the 2nd Respondent (hereinafter, the "MHA") and the National Disaster Management Authority (hereinafter, the "NDMA") under it, and the Ministry of Health and Family Welfare (hereinafter, "MoHFW"). These measures included the enforcement of lockdowns nationwide, and assistance and accelerated approvals for newly developed vaccines for the prevention of COVID-19. As part of its efforts, on 21.04.2021 the 1st Respondent issued Ext. P1, which states as follows:

"*Phase-I of the National Covid-19 Vaccination Strategy was launched on 16th January 2021 and focussed on protecting Health Care Workers (HCWs) and Front Line Workers (FLWs). Phase-II was initiated from 1st March 2021 and 1st April 2021 and focussed on protecting the most vulnerable i.e. population more than 45 years of age that accounts for more than 80% Covid mortality in the country…*

In its phase-III, the National Vaccine Strategy aims at liberalized vaccine pricing and scaling up of vaccine coverage. This would, on the

one hand, incentivize 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 ensure augmented vaccine production as well as wider availability of vaccines in the country.

The main elements of the Liberalised Pricing and Accelerated National Covid-19 Vaccination Strategy that would come in effect from 1st May 2021, are as follows:-

(i) *Vaccine manufacturers would supply 50% of their monthly Central Drugs Laboratory (CDL) released doses to Govt. of India and would be free to supply remaining 50% doses to State Govts. and in the other than Govt. of India channel.*

(ii) *Manufacturers would in a transparent manner make an advance declaration of the price for 50% supply that would be available to State Govts. & in the other than Govt. of India channel, before 1st May 2021. Based on this price, States, private hospitals, industrial establishments through their hospitals may procure vaccine doses from the manufacturers. Private Hospitals would have to procure their supplies of Covid-19 vaccine exclusively from the 50% supply earmarked for other than Govt. of India channel. The price charged for vaccination by private hospitals would be monitored.*

(iii) *Consequently the present dispensation where private Covid vaccination centres receive doses from Govt. and can charge up to Rs.250 per dose will cease to exist.*

(iv) *For Govt. of India vaccination centres, the eligible population would be the same which exists today i.e. Health Care Workers (HCWs), Front Line Workers (FLWs) and population above 45 years of age. For other than Govt. of India channel, the eligibility would be all adult citizens of the country i.e. everyone above the above of 18.*

(v) *Covid-19 vaccination will continue to be free for eligible population groups in all those Government Covid Vaccination Centres which receive vaccine doses from Govt. of India.*

(vi) *All vaccination (through Govt. of India vaccination centres and other than Govt. of India channel) would be part of the National Vaccination Programme, will follow all existing guidelines, will be captured on CoWIN platform alongwith the stocks and price per vaccination applicable in all vaccination centres, will comply with Adverse Event Following Immunization (AEFI) management and reporting, digital vaccination certificate & all other prescribed norms.*

(vii) *The division of vaccine supply 50% to Govt. of India & 50% to other than Govt. of India channel would be applicable*

uniformly across for all vaccines manufactured in the country.

(viii) *However, the fully ready to use imported vaccine would be allowed to be utilized entirely in the other than Govt. of India channel.*

(ix) *Govt. of India, from its share, will allocate vaccines to States/UTs based on the criteria of performance (speed of administration, average consumption), extent of infections (number of active Covid cases). Wastage of vaccine will also be considered in the criteria & will affect the allocation negatively. Based on the above criteria, State-wise quota would be decided and communicated to the States in advance.*

(x) *Second dose of all existing priority groups i.e. HCWs, FLWs and population above 45 years, where ever it has become due, would be given priority, for which a specific and focused strategy would be communicated to all stakeholders.*

(xi) *The Co-Win digital platform would be refined to reflect the aforesaid main elements.*

(xii) *This policy would come into effect from 1st May 2021 and will be reviewed from time to time.*

3. It is submitted that Ext. P1 has been issued without sufficient legal basis or backing. It is pertinent to note here that Ext. P1 Liberalised Strategy is not in the form of any Ordinance, order, bye-law, rule, regulation, notification, custom or usage having in the territory of India the force of law, and is merely an unsigned document which does not appear to have been issued under any law in force. The Constitution of India identifies "public health" to be a state subject under List II of Schedule VII. However, the MHA has notified COVID-19 pandemic to be a disaster under the Disaster Management Act, 2005 (hereinafter, the "DM Act"). "Disaster management" does not fall within the scope of any of the Lists under Schedule VII of the Constitution and is consequently a residual subject over which Parliament has the power to make laws and the 1st Respondent has executive power. However, while the 1st Respondent has been utilizing such powers in the manner prescribed under the DM Act with respect to measures such as lockdowns, there is no indication that the Liberalised Strategy has also been issued in that manner. The DM Act requires the 1st Respondent to put in place a National Plan. Such National Plan must be formulated after consultation with the States, as mandated under Section 11 of the DM Act. Accordingly, a National Plan under the DM Act was published in November 2019. However, the said National Plan does not make any mention of vaccination distribution strategy or vaccination price fixation. Therefore, if Ext. P1 is sought to be justified as having been issued in exercise of powers under the DM Act, then the existing National Plan needed to have been modified accordingly. Such modification would also have mandatorily required consultation with the States. However, Ext. P1 has been issued without any consultation with the States.

4. The right to health and medical care has been held to flow from the right to life under Article 21 of the Constitution of India by the Hon'ble Supreme Court in cases such as **Consumer Education & Research Centre v. Union of India**, reported in **1995 SCC (3) 42**. In **Paschim Banga Khet Mazdoor Samity v. State of West Bengal**, reported in **1996 SCC (4) 37**, the Apex Court held that it is the constitutional obligation of the State to provide adequate medical services to the people. It observed that whatever is necessary for this purpose has to be done, and that the State cannot avoid its constitutional obligation in the matter of discharge of its constitutional obligation to provide medical aid to preserve human life. The Supreme Court in **State of Punjab v. Ram Lubhaya Bagga**, reported in **(1998) 4 SCC 117** further observed that securing protection of one's life is one of the foremost obligations of the State, and that it is not merely a right enshrined under Article 21 but an obligation cast on the State to provide this both under Article 21 and under Article 47 of the Constitution. The obligation includes improvement of public health as its primary duty. It is further incumbent on the State under Part IV of the Constitution to minimise the inequalities in income, and endeavour to eliminate inequalities in status, facilities and opportunities, and direct its policies towards securing that the ownership and control of the material resources of the community are so distributed as best to subserve the common good and that the operation of the economic system does not result in the concentration of wealth and means of production to the common detriment. It is submitted that Ext. P1 Liberalised Strategy violates these fundamental rights and also the Directive Principles of State Policy enshrined in the Constitution under

Articles 47, 38, 39(b) and 39(c) by having the State step away from its primary duty, subverting the common good by securing ownership and control over material resources in the hands of a few, and leading to concentration of wealth and the means of production to the common detriment.

5. Through Ext. P1 Liberalised Strategy, the 1st Respondent is effecting a radical departure from its own established practices and policies, and also international best practices followed by nations who have more successfully tackled the pandemic than India. India has a long history of free and universal immunization against diseases, with a robust National Vaccine Policy and a Universal Immunisation Programme (hereinafter, "the UIP") through which the 1st Respondent provides vaccines against 12 diseases based on a National Immunization Schedule. A copy of the National Vaccine Policy is produced herewith and marked as **Exhibit P2**. A copy of the note made available by the 3rd Respondent regarding the Universal Immunisation Programme is produced herewith and marked as **Exhibit P3**. A copy of the National Immunization Schedule is produced herewith and marked as **Exhibit P4**. The UIP is fully funded by the Central Government, extending from procurement of the vaccines to cold storage and supplying them to the states. This practice was followed across the first two phases of the national vaccination strategy against COVID-19, where specific sets of high-risk individuals were provided the vaccines free of cost. However, under Ext. P1 Liberalised Strategy, the 1st Respondent proposes to release 50% of the vaccines manufactured in India into the open market, where states, private hospitals and industrial establishments through their

hospitals would compete against one another to procure them from manufacturers who have monopolies on their production, at price points set by the same manufacturers. This means that while some persons will continue to receive vaccines free of costs from places where the 1st Respondent delivers its own share of the vaccines, it has been left to the state governments and private healthcare providers to service all other persons who will not be fortunate enough to receive their vaccine doses for free.

6. Moreover, while Ext. P1 Liberalised Strategy opens up vaccinations for people who fall within the 18-45 age range, it does not allow them to obtain vaccines from the pool reserved by the 1st Respondent. Consequently, people belonging to this age group are reliant entirely on their respective state governments or private hospitals to provide them with vaccine doses. Wherever state governments choose not to provide vaccines from their own pool, which will naturally be smaller than the pool available to the 1st Respondent, to this age group free of cost, these persons will be left in a position where they have no means to obtain vaccines without paying for them. This amounts to discrimination against this group on the basis of age, and denial of their right to health. Thus, Ext. P1 Liberalised Strategy ex facie violates Articles 14, 15 and 21 of the Constitution of India.

Vaccine Rollout in India

7. It is submitted that since the origin of the COVID-19 pandemic in China, from where it spread across the world, governments in

various countries have tried many measures to combat the spread of the disease. This ranges from mask mandates to lockdowns (such as the one(s) imposed in India starting from 24.03.2020). However, the most effective strategy in combating the virus has been vaccination drives. Globally, vaccines have been developed and deployed by the pharmaceutical industry, universities, researchers, laboratories and governments at a fast pace. However, India lags far behind other nations of the world in terms of the percentage of the population vaccinated against COVID-19. As per the 1st Respondent's official statistics, as reported in the Cumulative Coverage Report issued by the MoHFW dated 27.04.2021, only 14,52,71,186 vaccine doses have been administered in the country, and only 2,39,10,177 persons have received both doses of either Covishield or Covaxin. A copy of the Cumulative Coverage Report issued by the MoHFW is produced herewith and marked as **Exhibit P5**. In comparison, 9,58,88,088 people have received both doses of the vaccine in the United States as of 26.04.2021, and 22,86,61,408 total doses have been administered. India also lags behind many other countries in terms of percentages, with less than 9% of our population having received at least one dose of the vaccine, compared to over 62% in Israel, 42% in the US, 49% in the UK etc. India lags behind even other developing nations of the world, such as Chile (41%), Hungary (38%), Uruguay (32%), Serbia (28%) etc. Moreover, while there is no information in the public domain regarding vaccine stocks, there have been reports of states expecting or facing shortages. It is submitted that the Petitioner is conscious of the fact that due to the large population in India it may not be fair to compare the international statistics on vaccination and the Petitioner does not wish to imply that Indian Government is not

making an earnest effort. The grievance highlighted in the present petition is to try and offer various suggestions and mechanisms whereby the vaccination can reach the maximum number within the shortest time resulting saving precious lives of the citizens of India.

8. Kerala has administered 71,07,072 vaccinations, of which 11,59,658 are second doses, indicating the total number of persons in the state who are fully vaccinated. As of 28.04.2021, Kerala has had 14,95,378 COVID-19 cases out of which 2,66,644 are active, and 5,212 persons are reported to have passed away due to the disease. The test positivity rate is above 15% in 12 of Kerala's 14 districts. On 28.04.2021, a day in which it reported over 35,000 new cases of COVID-19 (the highest tally yet) the Government of Kerala decided to purchase one crore doses of vaccine directly from the manufacturers under the Ext. P1 Liberalised Strategy.

9. In India, two vaccines are being deployed at present – Covishield (manufactured by the 7th Respondent) and Covaxin (manufactured by the 8th Respondent), with another, Sputnik-V, having recently gained approval, is being readied for deployment. There are several additional vaccine candidates at various stages of development, testing etc. at present – however, Ext. P1 Liberalised Strategy at this juncture will apply only to the products that are available in India, i.e., Covishield and Covaxin. The 7th Respondent is the sole manufacturer in India for Covishield, which was developed by the University of Oxford and AstraZeneca PLC on the basis of a not-for-profit licensing arrangement. In contrast, Covaxin was developed by the 3rd Respondent, a state-run body, in collaboration with the 8th

Respondent. Details regarding the specifics of either arrangement have not been released to the public domain. However, it may be noted that a technology transfer has been reported to have been effected by the 1st Respondent to the Haffkine Institute (which is a state-run institution in the State of Maharashtra) for the manufacture of Covaxin. It has also been reported that Indian Immunologicals Limited (IIL), Hyderabad, and Bharat Immunologicals and Biologicals Limited, Bulandshahr, two other state-run organisations, will also be provided with due clearances and support to manufacture Covaxin. This has been reported in the news article dated 20 April 2021 published in Livemint, produced herewith and marked as **Exhibit P6**. Thus, Covaxin has been developed through a collaboration between the 3rd Respondent and the 8th Respondent, which is reported to have included sponsorship on the part of the 1st Respondent. In such a case, under the terms of the General Financial Rules, 2017, a stipulation should be made that the ownership of the physical and intellectual assets created or acquired out of such funds shall vest in the sponsor. Therefore, the ownership of the intellectual property behind Covaxin should vest with the 1st Respondent.

Procurement and Pricing

10. Emergency authorisation was given by the 4th Respondent to both vaccines on 03.01.2021. Subsequently, the vaccines were rolled out by the 1st Respondent through Phases I and II of its national vaccine strategy, where the 1st Respondent was procuring doses from the 7th and 8th Respondents. While the specific details of the arrangements made by the 1st Respondent with vaccine

manufacturers have not been disclosed in the public domain, news reports place the procurement costs of both vaccines at around INR 150-200. Additionally, it is understood that the 1st Respondent has proposed to provide further financial assistance to both manufacturers to the tune of INR 4,500 crores in order to build capacity to expand vaccine production, as reported in the article dated 20 April 2021 published in the New Indian Express produced herewith and marked as **Exhibit P7**.

11. Following the release of Ext. P1 Liberalised Strategy, the 7th and 8th Respondents have both revised their rates on the basis of the split put in place thereby. As per the 7th Respondent, Covishield will be made available to the 1st Respondent at INR 150 per dose, to state governments at INR 300 per dose (revised from INR 400 per dose on 28.04.2021) and to private hospitals at INR 600 per dose. The 8th Respondent has announced that Covaxin will be made available at INR 150 per dose to the 1st Respondent, INR 600 per dose for state governments and INR 1200 per dose to private hospitals. It may be noted here that it has been reported that the price at which the 7th Respondent proposes to sell Covishield to private healthcare providers in India is the highest rate for this vaccine anywhere in the world. While this vaccine will cost around $8 per dose in India in the private hospital channel (and around $4 USD in the state government channels), the European Union is paying $2.15-$3.50 per dose, the UK around $3 per dose and the US has been offered the vaccine at $4 per dose, according to data compiled by the British Medical Journal. It has also been reported that Brazil will be paying $3.15 per dose for this vaccine through a state-owned licenced producer. The 8th Respondent

has stated that it proposes to export Covaxin for around $15-20. It may be noted that neither vaccine manufacturer has provided any rationale for the pricing, or any materials in relation to the same. There is no information available at present regarding their financial positions, costs of manufacture, or any externalities that require them to price vaccine doses at the rate that they currently do.

12. On 26 April 2021, the 2nd Respondent MHA issued a letter to state governments, urging the implementation of the MoHFW's containment framework which specifically mandates 100% vaccination for eligible age-groups within identified areas. A copy of the letter dated 26.04.2021 issued by the MHA is produced herewith and marked as **Exhibit P8**. However, as opposed to a free-and-universal immunization framework to support this effort, the respondents have created an extremely burdensome environment where states and private players must necessarily take on costs of procuring and providing vaccine doses or pass on such costs to recipients in order to meet such a mandate.

13. Further, as mentioned above, a vast majority of vaccine recipients in India are yet to receive their second dose. These are persons who received free vaccines under Phases I and II of the 1st Respondent's vaccine strategy, who may, in addition to now being required to compete against the newly-eligible 18-45 years age group for vaccination slots, also have to pay for their second doses which they would reasonably have expected to be provided free of cost. At present, this group of people are captive to the vaccine they have taken. These persons have a legitimate expectation to have their

vaccination process completed on the basis of the strategy followed by the 1st Respondent prior to the introduction of Ext. P1 Liberalised Strategy and on the basis of the terms on which they had received their first dose.

14. It is submitted that Ext. P1 Liberalised Strategy deliberately channels persons in the 18-45 years age group, which makes up a sizeable majority of India's population, towards paying for the vaccines, which goes against the principles and rationale behind adoption of universal immunisation in India. This is a discriminatory and arbitrary action involving non-application of mind on the part of the 1st Respondent, which has failed to give any rationale for why this group is being denied access to the vaccine doses allocated to the 1st Respondent, and also failed to consider that there may be persons who fall under this age group who are also in the high-risk category when it comes to COVID-19, such as persons with comorbidities. Moreover, disincentivising this age group from getting vaccinated can, especially in the light of the surge in COVID-19 cases and the severity with which certain new variants of the virus are affecting even younger people, lead to many persons choosing to forego the vaccine and acting as carriers of the virus, leading to a continuation of its spread, including delivering it to persons who fall outside their age group who fall under any of the at-risk groups.

15. India's poverty line was set at INR 972 per month in rural areas and INR 1407 per month in urban areas by the Rangarajan Committee in 2014, which estimated that around 29% of the nation's population lived below this line. While no official estimates have been

released post this period, some sources estimate that the pandemic-driven recession of the last year has led to at least 7.5 crore additional people living on less than $2 a day when compared to pre-pandemic levels. It is submitted that the 1st Respondent's new Liberalised Strategy delivers a devastating blow to India's poor, given their obvious inability to meet the new rates for vaccines set by the 7th and 8th Respondents, leaving them either without a real option to get vaccinated, or at best reliant on their state governments to eventually deliver vaccines to them at no cost.

Shortages

16. Very little information is available in the public domain as to the extent of stocks available to the 1st Respondent and various state governments from vaccine manufacturers at present. There have been several reports as to the non-availability of doses, and impending shortages due to depleting stock. As vaccine hesitancy lifts and more and more people come forward to get vaccinated, it is likely that the existing stocks and present production capacity of the 7th and 8th Respondents will not be sufficient to meet demand. In such a situation, it is imperative that capacity is increased by either requiring the present manufacturers to scale up or onboarding additional manufacturers. At present, it is reported that the 7th Respondent can manufacture between 6-7 crore doses per month, and the 8th Respondent can manufacture around 1 crore doses per month. Given the size of India's population, producing around 8 crore doses of vaccine per month will not be sufficient to meet the growing demands across the country, and it will be near impossible to flatten the rising COVID-19 curve in that case. Several state governments, including

those of Punjab, Rajasthan, Maharashtra, Kerala, and Jharkhand, have already expressed concerns regarding their depleted stores and inability to commence expanded rollout on the 01.05.2021 target date. India, being a hub of vaccine manufacturing, has several other organisations besides the 7th and 8th Respondents who have the capacity and have also been duly authorized to produce vaccines, thus providing a runway to expand the supply of vaccines in the country in the immediate future. The list of licensed human vaccine manufacturing facilities in India in both the private sector and under the Government, as made available by the 4th Respondent on its website, has been produced herewith and marked as **Exhibit P9**.

Inaction by the 1st Respondent

17. It is submitted that there are several legal options open to the 1st respondent which are intended to be utilised precisely in such situations. For instance, Section 26B of the Drugs and Cosmetics Act, allows the 1st Respondent to regulate or restrict the manufacture, sale or distribution of a drug if it believes that it is essential to meet the requirements of an emergency arising due to epidemic or natural calamities and it is necessary or expedient to do so in the public interest. The current pandemic is undoubtedly one such an emergency and it is a duty on the 1st Respondent to direct that all persons who have vaccine manufacturing capability should be utilizing them to the fullest to manufacture either Covishield or Covaxin.

18. The 1st Respondent also has the option of bringing vaccines under the scope of the Essential Commodities Act, 1955, under which

the 1st Respondent may, by order, provide for the regulation of the production, supply and distribution of essential commodities so that it may increase the supply for securing their equitable distribution and availability at fair prices. The Drugs (Prices Control) Order, 2013 (hereinafter, the "DPCO") was issued by the Central Government in exercise of powers conferred under Section 3 of the Essential Commodities Act, 1995, and pursuant to the National Pharmaceutical Pricing Policy, 2012 (NPPP-2012). The DPCO enables the 1st Respondent to fix ceiling prices for all medicines notified by it thereunder. The 1st Respondent is fully competent to extend such price ceilings to the COVID-19 vaccines. The Petitioner is not suggesting that the 1st Respondent must arbitrarily fix prices wherein manufacturers are denied profitability. Rather, ceiling prices must be fixed on the following basis, as extracted from the NPPP-2012::

"*(iv) The methodology of fixing a ceiling price of NLEM medicines, by adopting the Simple Average Price of all the brands having market share (on the basis of Moving Annual Turnover) more than and equal to 1% of the total market turnover of that medicine, will be as per the formula below: (Sum of prices of all the brands of the medicine having market share more than and equal to 1% of the total market turnover of that medicine) / (Total number of manufacturers producing such brands of the medicine).*

(v) The formulations will be priced only by fixing a Ceiling Price (CP). Manufactures would be free to fix any price for their products equal to or below the CP. The CP"s would be fixed on the dosage basis, such as per tablet/capsule/standard injection volume as listed in NLEM-2011.

(vi) The Ceiling Price will be fixed on the basis of readily monitorable Market Based Data (MBD). To begin with, the basis for this readily monitorable market data would be the data available with the pharmaceuticals market data specializing company – IMS Health (IMS). Wherever required this data would be checked by appropriate survey/evaluation by the National Pharmaceutical Pricing Authority (NPPA). As the IMS data gives price figures for stockiest level prices hence in order to arrive at ceiling Price (which will be the maximum retail price), the IMS price will be further increased by 16% as margin to the retailer so as to arrive at a reasonable ceiling price chargeable from the consumers."

These principles are embodied in the DPCO as well, as set out in the extracts below:

"*4. Calculation of ceiling price of a scheduled formulation.– (1) The ceiling price of a scheduled formulation of specified strengths and dosages as specified under the first schedule shall be calculated as under:*

Step1. First the Average Price to Retailer of the scheduled formulation i.e. P(s) shall be calculated as below:

Average Price to Retailer, P(s) = (Sum of prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one percent of the total market turnover on the basis of moving annual turnover of that medicine) / (Total number of such

brands and generic versions of the medicine having market share more than or equal to one percent of total market turnover on the basis of moving annual turnover for that medicine.)

Step2. Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as below: P(c) = P(s).(1+M/100), where

P(s) = Average Price to Retailer for the same strength and dosage of the medicine as calculated in step1 above. M = % Margin to retailer and its value =16 (2) The ceiling price calculated as per sub-paragraph (1) and notified by the Government shall be applicable to scheduled imported formulations also."

The DPCO also provides for calculation of reference data and source of market based data. Paragraph 9(1) of the DPCO states that initially the data available with IMS (Health) must be used. Paragraph 11 of the DPCO, 2013 expressly provides that the average price to retailer (PTR) shall be calculated on the dosage basis. It is important to note here that the DPCO implements a "One Drug, One Price" policy whereby drugs are always available at the same MRP across the country. Ext. P1 Liberalised Strategy is in violation of this policy. It may also be noted that both Covishield and Covaxin are being distributed and used on the basis of an emergency use authorization provided by the Subject Expert Committee of the 4th Respondent, which is only "*an approval for restricted use in emergency situation in public interest as an abundant precaution, in clinical trial mode, to have more options for vaccinations, especially in case of infection by mutant strains*", as informed by the 4th Respondent vide its Press

Statement dated 03.01.2021, produced herewith and marked as **Exhibit P10**. Neither vaccine has been approved for commercial marketing or sale in the ordinary course as they typically would have had to be in a non-pandemic situation.

18A. The 1st Respondent can also choose to make use of its powers under Section 2 of the Epidemic Diseases Act, 1897, under which it is empowered to take measures and prescribe temporary regulations to be observed by the public or by any person or class of persons to prevent the spread of any dangerous epidemic disease. Further, it can consider granting compulsory licences with respect to the vaccines to manufacturers other than the 7th and 8th Respondents under the Patents Act, 1970, wherein it is able to do so in circumstances of national emergency or extreme urgency, and make use of inventions for the purpose of Government. Powers such as these have vested in the 1st Respondent specifically for circumstances such as the pandemic at hand. Not utilizing them amounts to negligence on the part of the 1st Respondent, who is enabling privatization and profiteering over vaccines in a manner contrary to public interest.

The position of state governments

19. It is understood that in the 1st Respondent's Union Budget for FY 2021-22, an allocation of INR 35,000 crores has been made towards COVID-19 vaccines. The relevant portion of the speech of the Minister of Finance before the Parliament of India in relation to the budget allocation for COVID-19 vaccines is produced herewith and marked as **Exhibit P11**. In such a circumstance, and given the

arrangement followed in Phases I and II of the 1st Respondent's vaccination strategy and the historic practices followed by India and its Governments when it came to vaccinations, there was a legitimate expectation on the part of state governments that the 1st Respondent would cover the costs of procurement for vaccine doses. Instead, by enabling differential pricing by the vaccine manufacturers for procurement from the Centre (at INR 150 per dose) and states (at INR 300 and INR 600 per dose, depending on the vaccine), the 1st Respondent has gone against the spirit of cooperative federalism enshrined in the Constitution of India, and undertaken arbitrary and illegal actions that will ultimately lead to great harm to India's general populace. The 1st Respondent has pitted the states of the Union not just against private hospitals who will be able to pay a higher rate to vaccine manufacturers, but also against each other. It is also submitted that it is unprecedented for the same vaccine to be priced differently for the Centre, the states, and private players, and this patently goes against the practice of one drug, one price that has been followed till date. It is apparent on the face of it that this step is a means for the vaccine manufacturers to be able to make significantly higher profits. Further, by allowing the Centre to severely undercut states and private hospitals, the Liberalised Strategy is essentially enforcing a kind of cross-subsidisation for the 1st Respondent. Ultimately the burden to cross subsidise would fall on the Citizens of the country, since by permitting higher prices to be collected from the State Governments and Private Hospitals, they are being permitted to charge more from the citizens who get vaccinated through those channels.

20. Furthermore, it is submitted that there is no clarity on how the 7th and 8th Respondents propose to undertake the allocation of their stocks of vaccine doses between state governments and private hospitals, including industrial establishments through their hospitals. Ext. P1 Liberalised Strategy provides no clarity at present what the nature of procurement will be for such industrial establishments. Given the purchasing power and access that major corporations in India enjoy, and considering that these players would very much want their employees and associates to be able to work and move freely, it is likely that the workforces of such industrial establishments will be able to crowd out states by paying the prescribed higher prices for supplies from the vaccine manufacturers. Being private players themselves, the vaccine manufacturers have no greater obligation to strive for fair and equitable distribution of their products unless they are compelled to do so.

21. The vaccine manufacturers have already publicly stated their profit motive when it comes to the vaccines produced by them, as noted in interviews with senior executives of both companies, reports of which as published on 25 April 2021 by the Indian Express in the case of the 7th Respondent and 22 April 2021 by the Business Standard in the case of the 8th Respondent are produced herewith and marked as **Exhibit P12** and **Exhibit P13**. Hence, it is only natural that the larger margins available to them from private players are more attractive, and consequently the paid channels for vaccines, i.e. their distribution through private hospitals, is likely to be more robust than the implementation that is proposed to be undertaken by states, which is in many cases proposed to be free and universal. Therefore,

it is likely that the rich and privileged classes will have easier access to vaccines on a ready-to-pay basis, whereas India's less fortunate economic classes will be left waiting their turn, depending on the allocation process subjectively decided on and followed by the 7th and 8th Respondents. Further, even *inter se* state governments, purchasing power will vary on the basis of their revenues, cash at hand etc., which can lead to the residents of those states who are at a disadvantageous position in this respect being adversely affected. Moreover, states with more immediate relationships with the vaccine manufacturers, such as those states where their registered and corporate offices and manufacturing facilities are situated, may be able to use this to their advantage, thus adversely affecting other states. Thus, Ext. P1 Liberalised Strategy will, in addition to discrimination on the basis of age, lead to unequal protection before the law, additional discrimination on basis of class, place of birth and denial of the right to life of the persons adversely affected by the same.

Other Issues

22. It is submitted that the price point at which Covaxin will be made available to both state governments (i.e. INR 600 per dose) and private hospitals (i.e. INR 1200 per dose) is especially egregious, considering that it was developed with the active assistance of the 1st and 3rd Respondents, in the form of financial assistance and also knowledge capital from scientists who work for various organisations under the control of the 1st and 3rd Respondent, including the Director-General of the 3rd Respondent. It is also evident that the 1st Respondent has due competence to enable the production of Covaxin

by manufacturers other than the 8th Respondent. Whereas the 7th Respondent has stated publicly that it is a licensee who is manufacturing Covishield on the basis of royalty payments that are paid to the owners of intellectual property in that vaccine, there is no such compulsion on the part of the 8th Respondent. There is no information in the public domain available as to the reasons behind the high price points at which Covaxin is to be sold by the 8th Respondent. Given the role of the 1st and 3rd Respondents in its development, pricing Covaxin at a rate that makes it unaffordable for most of India and placing additional financial strains on state governments in order to procure it is arbitrary amd unconscionable. As stakeholders in the indigenous vaccine development process in India, state governments and the public at large have a reasonable expectation and entitlement to receive such indigenous vaccines (i.e. Covaxin) at affordable rates.

23. It is also submitted that the present enrolment scheme for vaccinations will further exacerbate the situation at hand. Coupled with vaccine shortages and supply chains in disarray, the CoWin system through which registrations are being carried out at present is not in a position to address the increased demand when registrations are opened to persons belonging to the 18-45 years age group. It is evident that the systems in place at present are not in a position to meet even existing demand. Through Ext. P1 Liberalised Strategy, the 1st Respondent will further open up the COVID-19 vaccine market to profiteering and black marketing, especially given the creation of a channel independent of the State.

24. The Hon'ble Supreme Court of India has taken *suo moto* cognizance of the COVID-19 situation in the country and has asked the 1st Respondent to explain the rationale behind the differential pricing strategy as well as how it is planning to meet the surge in vaccine demand. The Apex Court has also refused to interfere with High Courts hearing matters on the subject, stating that High Courts are best suited to make an assessment of ground realities in each States and find flexible solutions for problems faced by citizens. Thus, it is submitted that this Hon'ble High Court is not in any way barred from issuing any orders or granting any relief that it sees fit. By way of this PIL the Petitioner seeks to ensure that the residents in Kerala are, without any discrimination, able to get vaccinated in a time bound manner by ensuring adequate supply of vaccines, following a transparent mechanism, at reasonable cost without being exploited.

25. Hence, aggrieved by the absence of a universal vaccination program to mitigate and prevent the spread of the COVID-19 pandemic and by the arbitrary and illegal nature of Ext. P1 Liberalised Strategy, and fearful of the drastic consequences it can have on the people of India, and left with no other efficacious and alternative remedy than to approach this Hon'ble Court, the Petitioner begs to file this Public Interest Litigation on the following among other:

GROUNDS

A. The Constitution of India guarantees to persons a right to health, as recognised by the Hon'ble Supreme Court of India in cases such as Consumer Education & Research Centre (supra). This

right extends to placing a legal obligation on the State to ensure a reasonable and equitable access to life-saving drugs to patients, according to the Hon'ble High Court of Delhi in **Mohd. Ahmed (Minor) v. Union of India**, as reported in **2014 SCC OnLine Del 1508**. In the present COVID-19 pandemic situation, the vaccines being rolled out in India are at their very core, life-saving drugs that must be provided on a reasonable and equitable basis. The 1st Respondent's Ext.1 Liberalised Strategy goes against this fundamental proposition and is thus *ultra vires* Article 21. This further falls afoul of the directive principles applicable to the 1st Respondent, enshrined in Articles 47, 38, 39(b) and 39(c) of the Constitution.

B. The legal framework under which the Liberalised Strategy has been put in place is not clear. The subject matter of the Liberalised Strategy is the distribution of vaccinations against COVID-19 in India, which is typically a matter of public health which falls under List II of Schedule VII of the Constitution and is a state subject. If the 1st Respondent has instead issued in exercise of its powers over disaster management, which is a residual subject, it must necessarily be in compliance with the DM Act. However, Ext. P1 Liberalised Strategy is merely in the form of a document that has been uploaded to the website of the 3rd Respondent, and is not in the form of any Ordinance, order, bye-law, rule, regulation, notification, custom or usage having in the territory of India the force of law. It does not mention that it is issued in exercise of any other source of power. It is unclear why state governments and private hospitals in India must be

bound by it. As held by the 9-judge bench of the Hon'ble Supreme Court of India in **Justice KS Puttaswamy Vs Union of India** reported in **2017 (10) SCC 1**, a three-pronged test must be satisfied by the state if it seeks to invade someone's rights under Article 21 of the Constitution, namely legality, legitimate state interest and proportionality. Given that the impugned Ext. P1 is without any legislative backing, it fails at the very first instance, since its legality itself is in question since it does not appear to have been issued under any law in force.

C. If Ext. P1 Liberalised Strategy has been issued under the DM Act, it must further be compliant with the National Plan formulated in consultation with state governments and expert bodies in the field. It is also the obligation of the Central Government to make provisions for financing the measures to be carried out under the National Plan. However, the National Disaster Management Plan, 2019 which was issued by the NDMA does not address vaccination drives to combat epidemics or pricing thereof. Therefore, there is no competence on the part of the 1st Respondent to issue Ext. P1 Liberalised Strategy or bind state governments thereto.

D. It is submitted that Ext. P1 Liberalised Strategy runs contrary to India's long history of universal and free immunization programs, as embodied in the UIP and the National Vaccine Policy. These, in combination with statements and promises from concerned persons related to the 1st Respondent, and the fact that this was the practice followed in the first two phases of the

1st Respondent's vaccination strategy, led to legitimate expectations among both state governments and the public that the vaccines would be procured by the 1st Respondent and distributed down the chain to the public free of cost and universally, in a gradually phased manner.

E. The sudden deviation vide Ext. P1 Liberalised Strategy contrary to the legitimate expectations in play is arbitrary and illegal. Legitimate expectation is a substantive, enforceable and protectible interest as a facet of Article 14 of the Constitution of India, as observed by the Hon'ble Supreme Court in **M.P. Oil Extraction v. State of M.P**, reported in **(1997) 7 SCC 592**. Recently, the Hon'ble Supreme Court of India has also stated in **State of Jharkhand v. Brahmputra Metallics Limited**, reported in **2020 SCC OnLine SC 968** that when the policies of the State give rise to legitimate expectations, the State cannot act in contravention of the same. The Hon'ble Supreme Court specifically stated that the State's policies "*give rise to legitimate expectations that the State will act according to what it puts forth in the public realm. In all its actions, the State is bound to act fairly, in a transparent manner. This is an elementary requirement of the guarantee against arbitrary state action which Article 14 of the Constitution adopts*".

F. The Hon'ble Delhi High Court, in the case of **GNCT of Delhi v. Naresh Kumar**, W.P.(C) 4769/2010, found that failure to consider or give due weightage to legitimate expectations of a citizen may render a decision to be arbitrary. Further, if an administrative authority proposes to defeat a person's legitimate

expectation, it should afford him an opportunity to make a representation in the matter. There must also be some rational ground for withdrawing the expected benefit. It is submitted that there was a failure on the part of the 1st Respondent to consider and give due weightage to these expectations and the rights of persons under the Constitution of India. Further, the 1st Respondent neither heard affected persons nor provided rational grounds to deviate from the established practice, under which benefits had accrued to citizens. The persons who got the first dose has a legitimate right to get the second dose at the same rate for which the first dose was taken and this legitimate right could not have been deprived by way of a press release issued by the 1st Respondent. Therefore, such deviation by the 1st Respondent through issuing the impugned Ext. P1 is arbitrary and illegal.

G. Further, there is non-application of mind by the 1st Respondent in attempting to pass the burden of procuring vaccines to state governments at short notice. Unlike private players who can distribute the vaccines at cost or on a for-profit basis, state governments will now need to supplement the supplies arriving from the 1st Respondent with their own procurement, and will be compelled to distribute what they procure for free at their own cost in order to ensure that people who cannot afford to buy the vaccines are also immunized. For a small State like Kerala, which had to face severe natural calamities by way of unprecedented floods and rainfalls with its depleted State exchequer, notice of a mere 10 days is not sufficient for this,

which is evident from the fact that state governments have only just begun to place orders with the 7th and 8th Respondents. The impugned Ext. P1 also does not take into consideration the stores procurement processes that have been put in place by each state governments, effectively requiring states to either bypass their own safeguards or fall behind other competing states and private players in obtaining vaccine doses for itself. Moreover, creating multiple procurement channels and supply chains for all state governments and private players will lead to unnecessary duplication, which will further slow down the vaccine distribution process and contribute to further spread of COVID-19.

H. It is submitted that in issuing the impugned Ext. P1, the 1st Respondent has also not considered any scenario where a state government does not have the financial capacity to procure additional doses of vaccines for themselves. The right to life of persons gives rise to obligations on the part of both the central and state governments. Therefore, if the state government is in a position where it cannot afford to buy the vaccines, it is the legal duty of the central government to ensure that the residents of the state get the vaccines. The central government cannot excuse itself from this responsibility by passing the buck to state governments alone, since it has assumed competence for itself in this domain by publishing the impugned policy to regulate vaccine distribution. Thus, at the very least, the 1st Respondent has an obligation to stand as guarantor for state governments in the procurement process and ensure that adequate supply of

vaccines to Kerala is ensured without insisting on upfront payment by the State Government. Moreover, under Section 46 of the DM Act, the Central and State Governments are expected to constitute a National Disaster Management Fund precisely for situations such as these. Furthermore, under Section 50 of the DM Act, where the NDMA or the State Disaster Management Authority is satisfied of the need for immediate procurement of provisions or materials, it has the power to arrange for such emergency procurement. This power also ought to have been exercised in the present situation.

I. The principles of the UIP are extremely relevant in the case of COVID-19, since herd immunity must be achieved through getting the vaccine to a critical mass of people. The price barriers erected by the Ext. P1 Liberalisation Strategy runs contrary to the principles of universal immunisation, and will lead to only a gradual and slow increase in the number of persons in India receiving the vaccine. The ensuing demand-supply inequivalence can lead to a panic situation among the citizens of the country, and also have dire economic consequences in addition to not being able to prevent loss of lives.

J. The impugned Ext. P1 Liberalisation Strategy also puts in place a completely arbitrary price fixation process, where the 1st Respondent has secured its own self-interest by obtaining 50% of vaccine doses from the 7th and 8th Respondents at discounted fair price but allowing the manufacturers to set the price at which the remaining doses are sold to the state governments and

private players. Neither the 7th or 8th Respondent has been forthcoming with any material information relating to the price fixation process, such as any insight into the costs of manufacture or their financial positions. It is estimated that the manufactures will earn tens of thousands of crores of rupees on the basis of the Ext. P1 Liberalisation Strategy. Given that at present these manufacturers are monopolists, it is submitted that they are abusing their position in the market to price gouge.

K. It is submitted that the public have already contributed financially to the development of the vaccines, in terms of the financial investment that has gone towards the manufacturers at the development and clinical trial states from the 1st Respondent, and also in terms of knowledge capital from research produced by persons such as scientists employed by the 3rd Respondent. Despite this, the rates at which these vaccines are being provided to the state governments and private players are among the highest in the world.

L. The right to healthcare and access to medicines under Article 21 has been upheld in the case of life-saving drugs. In **Union of India v. K.S. Gopinath**, **SLP(C)No. 3668 OF 2003**, the Hon'ble Supreme Court ordered that the 1st Respondent must consider and formulate appropriate criteria for ensuring essential and life saving drugs do not fall out of price control. The COVID-19 vaccines fall squarely within the scope of such life-saving drugs. The 1st Respondent has a duty to issue appropriate orders and/ or undertake appropriate measures under the

Essential Commodities Act, 1955, and the DPCO so that it may fix a price ceiling and increase the supply of the vaccines produced by the 7th and 8th Respondents for securing their equitable distribution and availability at fair prices. The 1st Respondent may also issue appropriate orders under Section 26B of the Drugs and Cosmetics Act, to regulate the manufacture, sale or distribution of the vaccines in question, given that such orders are essential to meet the requirements of the present emergency, which has arisen due to an epidemic and that it is very clearly necessary/ expedient to do so in the public interest. The 1st Respondent is also empowered to take measures and prescribe temporary regulations to be observed by the public or by any person or class of persons to prevent the spread of any dangerous epidemic disease. It is also within its powers to grant compulsory licences with respect to the vaccines to manufacturers other than the 7th and 8th Respondents under the Patents Act, 1970, given that it is a time of national emergency. This is all the more relevant in light of the fact that Covaxin, which was developed with the investment of money and knowledge capital of the State, currently has a sub-optimal rate of production due to it only being manufactured by the 8th Respondent at present. It is submitted that powers such as these have vested in the 1st Respondent in order to ensure the needs of the public during situations exactly like the pandemic at hand. The 1st Respondent has been negligent in failing to exercise these powers, and has instead enabled privatization and profiteering over vaccines by monopolists in a manner contrary to public interest.

M. It is submitted that Ext. P1 Liberalised Strategy has imposed differential pricing for vaccine doses being procured by the 1st Respondent, the state governments, and private players, in a manner that is directly in contravention of the "One Drug, One Price" practice that has been followed till date in all successful immunisation campaigns that have been carried out in India. This is a violation of Article 14 of the Constitution of India, and clearly fails the twin tests of reasonable classification that have been relied upon from the time of the Hon'ble Supreme Court's landmark verdict in **State of West Bengal v. Anwar Ali Sarkarhabib Mohammed**, reported in **AIR 1952 SC 75**. It is submitted that there is no intelligible differentia between the Centre and the State in the context of the procurement model put in place by Ext. P1 Liberalised Strategy, and to that end it here is no rationale that has been provided for the differential pricing in effect thereunder. This is arbitrary on the face of it and therefore, Ext. P1 must be quashed.

N. It has been left to the 7th and 8th Respondents to allocate 50% of the vaccine pool *inter-se* state governments and private players. It is evident from the respective prices under which they are providing Covishield and Covaxin that it is more profitable for them to sell to private players than it is to state governments. Further, they are also able to sell stock for export purposes, which will further limit the pool of vaccines available for domestic supply. Ext. P1 effectively incentivises the 7th and 8th Respondent to sell their stock to private players who have capital

and are interested in dealing on a for-profit basis. This can lead to state governments not being able to obtain stock of the vaccines even if they are ready to procure them at the prescribed rates. Furthermore, there is a real risk that larger states with more purchasing power or bigger markets may shut out smaller states, considering the volumes of orders that can be placed by them. Moreover, states with more immediate relationships with the vaccine manufacturers, such as those states where their registered and corporate offices and manufacturing facilities are situated, can exert pressure to get allocated doses and they may be able to use this to their advantage. Given that the vaccine manufacturers can essentially develop their own criteria for allocation of 50% of the stock produced by them between state governments, private players and export, the impugned Ext. P1 Liberalised Strategy effectively empowers the 7th and 8th respondents to make decisions regarding the lives of millions of people through opaque means. This runs contrary to any sort of national or public interest. At the core of these issues is the fundamental problem that the 1st Respondent has undertaken a completely arbitrary action in leaving decisions of which states and private players to prioritise in supply of vaccines to the unregulated subjective discretion of the manufacturers themselves. Moreover, when states are pitted against each other in claiming vaccines for their people in the manner envisioned under Ext. P1 Liberalised Strategy, it will inevitably mean that whenever one state is preferred over another, the more vulnerable residents of the latter lose out on vaccines but less vulnerable residents of the former get the vaccine. Those with

comorbidities may lose out on essential vaccines because their State could not compete successfully with other States. This is not a reasonable or fair way to distribute vaccines and will violate the Article 21 rights of the persons living in those states.

O. It is submitted that Ext. P1 Liberalisation Strategy's move to effectively deny free vaccination to persons in the 18-45 years age group is arbitrary and illegal. Ext. P1 blocks off people belonging to this age group from 50% of the vaccine supply in the country and further places the burden of bringing them within the ambit of free coverage on state governments, if they choose to do so. This means that persons belonging to this age group are reliant entirely on their respective state governments or private hospitals to provide them with vaccine doses. Wherever state governments choose not to provide vaccines from their own pool, which will naturally be smaller than the pool available to the 1st Respondent, to this age group free of cost, these persons will be left in a position where they have no means to obtain vaccines without paying for them. The distinction between this age group and those that are older in the context of paid versus free vaccination is not reasonable, given that people falling within this age group can have comorbidities that place them at a higher risk than older persons who do not have such issues. The 1st Respondent's non-application of mind has led to them having failed to consider such cases, and has led to a violation of their rights under Articles 14, 15 and 21 of the Constitution.

P. Moreover, it submitted that it is not rational to disincentivise people within this age group, who are active and out and about in society in general, from taking vaccinations, since it is highly likely that this age group makes up a critical mass of carriers of the virus, and therefore the spread of COVID-19 can only be arrested by ensuring that this group gains immunity. If they are not made part of a free and universal vaccination programme, the 1st Respondent will not be able to protect elder age groups from the COVID-19 virus, given the evident truth that the rate of spread of the virus is many times higher than the rate at which people are being vaccinated, and therefore it is more likely that persons above 45 years of age receive viruses from persons within the 18-45 age group than it is that they receive vaccines from the 1st Respondent.

On these and other grounds to be urged at the time of hearing, it is most humbly prayed that this Hon'ble Court may be pleased to allow this Writ Petition by granting the following:

RELIEFS

1. Call for the records leading to the issuance of Ext. P1 Liberalised Strategy and issue a writ of certiorari to quash Ext. P1 Liberalised Strategy;

2. Issue a writ of mandamus or any other appropriate writ, order or direction directing the 1st Respondent to: (i) bring the COVID-19 vaccines under the ambit of the UIP and follow the National Vaccine Policy in their deployment; (ii) carry out procurement and distribution of all COVID-19 vaccines by bearing all costs in

this regard, consistent with past practice; and (iii) roll out the COVID-19 vaccines free of cost across all age groups, including those between 18 and 45 years of age;

3. Issue a writ of mandamus or any other appropriate writ, order or direction directing the 1st Respondent to bring all COVID-19 vaccines under the ambit of the Drugs (Prices Control) Order, 2013 issued under the Essential Commodities Act;

4. Issue a writ of mandamus or any other appropriate writ, order or direction directing the 11th and 12th Respondents to allocate sufficient funds for procuring the vaccines for the State of Kerala so that vaccination can be done in a time-bound manner ; and

5. Grant such other reliefs that are deemed fit and proper given the facts and circumstances;

INTERIM RELIEF

1. Direct the 1st respondent to produce the records relating to the decision made to follow the pricing policy indicated in Ext. P1;

2. Direct the 7th and 8th respondents to produce the details of the calculation of costs, profits etc. based on which they have notified prices for vaccinations pursuant to Ext. P1, if required in a sealed cover, in the event of any confidentiality clauses being in existence for revealing such information in the public domain;

3. Direct the 1st Respondent to continue with its current policy of central procurement of all vaccines and free supply to the states with respect to COVID-19 vaccines;

4. Direct the 1st Respondent to ensure that the rates at which COVID-19 vaccines are administered continue to be no more than Rs. 250 per dose in private hospitals as was being done from the date of commencement of the vaccination drive;

5. Direct the 1st Respondent to ensure that persons who are eligible as on the date of this petition to receive free COVID-19 vaccination continue to remain eligible for the same despite the issuance of Ext. P1;

6. Direct the 1st Respondent to ensure that persons who have already received the first dose of COVID-19 vaccines will continue to be able to receive the second dose free of cost or at the same rate they received the first dose;

7. Direct the 1st Respondent to ensure that it provides adequate guarantee facility to states so that states are not stopped from obtaining adequate number of vaccines under Ext. P1 even if they do not have the capability to make upfront/ advance payments;

8. Direct the State Government to furnish the following details: (1) status report on the availability of vaccines in the state; (2); the number of persons who have taken first dose for free and are awaiting the second dose; (3) the number of persons who have taken first dose @250 per dose and are awaiting the second dose; (4) the number of persons above the age of 18 who are

yet to vaccinated in the State of Kerala who will have to be compulsorily vaccinated; (5)the funds required for procuring the vaccines from the central government as per the revised pricing; (6) the funds presently available in the State Exchequer at its disposal which can be earmarked for the procurement of the vaccines; (7) steps taken by the State Government for procuring the vaccines and the present status regarding the same; pending disposal of this Writ Petition

Dated this the 29th day of April, 2021.

Sd/-
PETITIONER

Sd/-
COUNSEL FOR THE PETITIONER

BEFORE THE HON'BLE HIGH COURT OF KERALA AT ERNAKULAM

W.P.(Civil)No. of 2021
(Special Original Jurisdiction)

Mathew Nevin Thomas	:	Petitioner
v.		
Union of India and others	:	Respondents

AFFIDAVIT

I, Mathew Nevin Thomas, aged 25 years do hereby, solemnly affirm and state as follows:-

1. I am the Petitioner in the above Writ Petition and I know the facts of the case. I am competent to swear to this affidavit. them.

2. The averments contained in the above Writ Petition (Civil) are true to the best of our knowledge, information and belief.

3. The Exhibits produced along with the above Writ Petition (Civil) are true copies of its originals.

4. I have not filed any other Petition before this Hon'ble Court, seeking the same relief earlier.

5. I am seeking to espouse a public cause and I have no personal or private interest in the matter and there is no authoritative pronouncement by the Supreme Court or the High Court on the question raised and that the result of the litigation will not lead to any undue gain to myself or to anyone associated with me. I have not filed any other public interest litigation in any other court before.

6. It is therefore prayed that this Hon'ble Court may be pleased to grant the reliefs prayed for in the above Writ Petition (Civil).

The above facts are true,

Dated this the 29th day of April, 2021.

Sd/-
Deponent

Solemnly affirmed and signed before me by the deponent on this the 29th day of April, 2021, in my office at Ernakulam.

Sd/-
Advocate

BEFORE THE HON'BLE HIGH COURT OF KERALA AT ERNAKULAM

W.P.(Civil) No. of 2021

(Special Original Jurisdiction)

Mathew Nevin Thomas	:	Petitioner
v.		
Union of India and others	:	Respondents

SYNOPSIS

List of Dates and Events

Sl. No.	Date	Event
1.	01.03.2020	First diagnosed case of COVID-19 reported in the State of Kerala
2.	24.03.2020	Nationwide lockdown imposed by the 1st Respondent
3.	03.01.2021	Authorization granted to Covishield and Covaxin by 4th Respondent
4.	16.01.2021	Phase I of nationwide vaccine strategy commences
5.	01.03.2021	Phase II of nationwide vaccine strategy commences
6.	21.04.2021	1st Respondent issues the *Liberalised Pricing and Accelerated National Covid-19 Vaccination Strategy* for Phase III of the nationwide vaccine strategy

The Petitioner herein is approaching this Honourable Court in public interest, seeking *inter alia* to challenge the 1st Respondent's *Liberalised Pricing and Accelerated National Covid-19 Vaccination*

Strategy which has overlooked well-settled constitutional principles as well as the fundamental rights of Indian citizens. Under the impugned Strategy, 50% of all COVID-19 vaccines produced in the country would be procured by the 1st Respondent at a discounted rate from vaccine manufacturers, and state Governments and private players would then procure vaccine doses from the remaining pool at higher price points. The 7th and 8th Respondents are the exclusive manufacturers (as of now) of Covishield and Covaxin, which are the only two vaccines that are being provided to persons in India at the moment. The impugned Strategy would allow the 7th and 8th Respondents to profit greatly from the sale of vaccine doses, but would have adverse effects on the public and would run contrary to the general wellbeing of India's citizens who are suffering from a pandemic that has raged in the country for over a year now.

It is submitted that the impugned Strategy has been issued without sufficient legal basis or backing. It is pertinent to note here that the impugned Strategy is not in the form of any Ordinance, order, bye-law, rule, regulation, notification, custom or usage having in the territory of India the force of law, and is merely a "press release", i.e. an unsigned document which does not appear to have been issued under any law in force. While "public health" to be a state subject under List II of Schedule VII, "Disaster management" is a residual subject over which Parliament has the power to make laws and the 1st Respondent has executive power. 1st Respondent has been utilizing such powers in the manner prescribed under the Disaster Management Act, 2005, with respect impugned Strategy has also been issued in that manner. This Act requires the 1st Respondent to put in place a

National Plan formulated after consultation with the States. However, the said National Plan does not make any mention of vaccination distribution strategy or vaccination price fixation. Therefore, if the impugned Strategy is sought to be justified as having been issued in exercise of powers under the DM Act, then the existing National Plan needed to have been modified accordingly. Such modification would also have mandatorily required consultation with the States. However, the impugned Strategy has been issued without any consultation with the States.

Further, the right to health and medical care has been held to flow from the right to life under Article 21 of the Constitution of India by the Hon'ble Supreme Court, which has also held that it is the constitutional obligation of the State to provide adequate medical services to the people. The impugned strategy violates fundamental rights enshrined in Part III of the Constitution and also the Directive Principles of State Policy enshrined in Part IV thereof, including in relation to minimising the inequalities in income, eliminating inequalities in status, facilities and opportunities, and securing that distribution of ownership and control of material resources of the community serves the common good and that the operation of the economic system does not result in the concentration of wealth and means of production to the common detriment.

The impugned Strategy is a radical departure from the 1st Respondent's own established practices and policies. India has a long history of free and universal immunization against diseases, with a robust National Vaccine Policy and a Universal Immunisation

Programme, which is what was followed by the 1st Respondent so far prior to the notification of the impugned Strategy. States, private hospitals and industrial establishments would need to compete against one another to procure vaccines from manufacturers who have monopolies on their production. Both Covishield and Covaxin have been priced at high rates in the non-Central Government pool. Further, many persons who are awaiting a second dose of vaccine after receiving their first dose may now be put in a position where they are captive to the vaccine they have taken but are also not able to afford the second dose at the notified rates, with the impugned Strategy going against their legitimate expectations. Moreover, persons from the age group 18-45 years old have been excluded from the ambit of the 1st Respondent's channels for vaccination altogether, meaning that they are being directed towards purchasing them from private players if they are not able to receive them from State Government channels. This age group can include people who belong to high risk categories due to comorbidities who have been deprioritised due to the 1st Respondent's non-application of mind. This amounts to discrimination against this group on the basis of age, and denial of their right to health. Thus, the impugned Strategy ex facie violates Articles 14, 15 and 21 of the Constitution of India.

As opposed to a free-and-universal immunization framework to support this effort, the respondents have created an extremely burdensome environment where states and private players must necessarily take on costs of procuring and providing vaccine doses or pass on such costs to recipients in order to meet such a mandate. The impugned Strategy thus also delivers a devastating blow to India's

poor, given their obvious inability to meet the new rates for vaccines set by the 7th and 8th Respondents, leaving them either without a real option to get vaccinated, or at best reliant on their state governments to eventually deliver vaccines to them at no cost.

There are several legal options open to the 1st respondent which are intended to be utilised precisely in such situations, including Section 26B of the Drugs and Cosmetics Act, 1940, the Essential Commodities Act, 1955 and price control orders thereunder, temporary regulations under the Epidemics Act, 1897 and compulsory licensing under the Patents Act, 1970. Not utilizing them amounts to negligence on the part of the 1st Respondent, who is enabling privatization and profiteering over vaccines in a manner contrary to public interest.

The 1st Respondent has pitted the states of the Union not just against private hospitals who will be able to pay a higher rate to vaccine manufacturers, but also against each other. It is also submitted that it is unprecedented for the same vaccine to be priced differently for the Centre, the states, and private players, and this patently goes against the practice of one drug, one price that has been followed till date. There is also no clarity on how the 7th and 8th Respondents propose to undertake the allocation of their stocks of vaccine doses between state governments and private hospitals, including industrial establishments through their hospitals. Being private players themselves, the vaccine manufacturers have no greater obligation to strive for fair and equitable distribution of their products unless they are compelled to do so. At the very least, the 1st Respondent has an obligation to stand as guarantor for state governments in the

procurement process and ensure that adequate supply of vaccines to Kerala is ensured without insisting on upfront payment by the State Government. Moreover, under Section 46 of the DM Act, the Central and State Governments are expected to constitute a National Disaster Management Fund precisely for situations such as these. Furthermore, under Section 50 of the DM Act, where the NDMA or the State Disaster Management Authority is satisfied of the need for immediate procurement of provisions or materials, it has the power to arrange for such emergency procurement. This power also ought to have been exercised in the present situation.

Further, is no information in the public domain available as to the reasons behind the high price points of either vaccine. The pricing of Covaxin is especially egregious. Given the role of the 1st and 3rd Respondents in its development, pricing Covaxin at a rate that makes it unaffordable for most of India and placing additional financial strains on state governments in order to procure it is unconscionable. As stakeholders in the indigenous vaccine development process in India, state governments and the public at large have a reasonable expectation and entitlement to receive such indigenous vaccines (i.e. Covaxin) at affordable rates.

List of Acts and Decisions

Sl. No.	Acts
1.	Disaster Management Act, 2005
2.	Drugs and Cosmetics Act, 1940
3.	Essential Commodities Act, 1955
4.	Epidemics Act, 1897
5.	Patents Act, 1970
	Cases
1.	Consumer Education & Research Centre v. Union of India, 1995 SCC (3) 42
2.	Paschim Banga Khet Mazdoor Samity v. State of West Bengal, 1996 SCC (4) 37
3.	State of Punjab v. Ram Lubhaya Bagga, (1998) 4 SCC 117
4.	Mohd. Ahmed (Minor) v. Union of India, 2014 SCC OnLine Del 1508
5.	M.P. Oil Extraction v. State of M.P, (1997) 7 SCC 592
6.	State of Jharkhand v. Brahmputra Metallics Limited, 2020 SCC OnLine SC 968
7.	GNCT of Delhi v. Naresh Kumar, W.P.(C) 4769/2010
8.	Union of India v. K.S. Gopinath, SLP(C)No. 3668 OF 2003
9.	State of West Bengal v. Anwar Ali Sarkarhabib Mohammed, AIR 1952 SC 75
10.	Justice KS Puttaswamy v. Union of India, 2017 (10) SCC 1

Dated this the 29th day of April, 2021.

Sd/-
Counsel for the Petitioner.

BEFORE THE HON'BLE HIGH COURT OF KERALA AT ERNAKULAM

W.P.(Civil) No. of 2021

(Special Original Jurisdiction)

Mathew Nevin Thomas : Petitioner

v.

Union of India and others : Respondents

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11	**Exhibit P8:** True copy of the letter dated 26.04.2021 issued by the MHA.	
12	**Exhibit P9:** True copy of the list of licensed human vaccine manufacturing facilities in India in both the private sector and under the Government, as made available by the 4th Respondent on its website.	
13	**Exhibit P10:** True copy of the Press Statement dated 03.01.2021 of the 4th respondent.	
14	**Exhibit P11:** True copy of the relevant portion of the Budget Speech in 2021.	
15	**Exhibit P12:** True copy of the News Report dated 25-4-2021 published by Indian Express.	
16	**Exhibit P13:** True copy of the News Report dated 22-4-2021 published by Business Standard.	

Dated this the 29th day of April, 2021.

Sd/-
COUNSEL FOR THE PETITIONER

Presented on: 29-04-2021

Subject ***"PIL –Challenging the Government of India's Liberalised Pricing and Accelerated National Covid-19 Vaccination Strategy and the consequent actions undertaken by vaccine manufacturers in India."***

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MEMORANDUM OF WRIT PETITION (CIVIL) FILED UNDER ARTICLE 226 OF THE CONSTITUTION OF INDIA

C.F. Rs. /- is paid

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