## IN THE HIGH COURT OF KERALA AT ERNAKULAM PRESENT

#### THE HONOURABLE THE CHIEF JUSTICE MR.S.MANIKUMAR

&

# THE HONOURABLE MR. JUSTICE SHAJI P. CHALY FRIDAY, THE 3RD DAY OF DECEMBER 2021 / 12TH AGRAHAYANA, 1943 WA NO. 1219 OF 2021

[AGAINST THE JUDGMENT IN W.P.(C) NO.16501/2021 DATED 03.09.2021 OF HIGH COURT OF KERALA]

#### APPELLANT/ADDL. 4TH RESPONDENT:

THE SECRETARY TO GOVERNMENT DEPARTMENT OF HEALTH AND FAMILY WELFARE, GOVERNMENT OF INDIA, NEW DELHI.

BY ADVS. SHRI P.VIJAYAKUMAR, ASG OF INDIA SRI. JAISHANKAR V. NAIR, CGC

#### RESPONDENTS/WRIT PETITIONERS & RESPONDENTS 1, 2 & 3:

- 1 KITEX GARMENTS LIMITED,
  KIZHAKKAMBALAM P.O., POST BOX NO.5,
  ERNAKULAM-683562,
  REPRESENTED BY ITS HR MANAGER,
  SATHEESH KURUP R.
- 2 KITEX CHILDRENSWEAR LTD..
  KIZHAKKAMBALAM P.O., POST BOX NO.5,
  ERNAKULAM-683 562,
  REPRESENTED BY ITS HR MANAGER, SATHEESH KURUP R.
- 3 STATE OF KERALA
  REPRESENTED BY PRINCIPAL SECRETARY,
  HEALTH AND FAMILY WELFARE DEPARTMENT,
  GOVERNMENT SECRETARIAT,
  THIRUVANANTHAPURAM-695 001.
- 4 THE DIRECTOR
  STATE HEALTH MISSION, GENERAL HOSPITAL JUNCTION,
  THIRUVANANTHAPURAM-695 035.

5 DISTRICT MEDICAL OFFICER (HEALTH)
PARK AVE, MARIND DRIVE, ERNAKULAM-682 011.

R1 & R2 BY ADV. BLAZE K.JOSE R3, R4 & R5 BY SENIOR GOVERNMENT PLEADER SRI. V.MANU,

THIS WRIT APPEAL HAVING COME UP FOR ADMISSION ON 03.12.2021, THE COURT ON THE SAME DAY DELIVERED THE FOLLOWING:

#### **JUDGMENT**

#### S. Manikumar, CJ

Instant writ appeal is filed by the Secretary to the Government,

Department of Health and Family Welfare, Government of India, New

Delhi, additional 4<sup>th</sup> respondent before the writ court, against the

judgment dated 3.9.2021 in W.P.(C) No.16501 of 2021, by which, a

learned single Judge allowed the writ petition, observing as under:

"7. The petitioners in the instant case maintain and agree with the Governments at the Central and State level that vaccination is absolutely necessary to overcome the global pandemic, Covid-19. As indicated, the petitioners do not have a case that a second dose of Covishield vaccine after 12 weeks, but within 16 weeks would not give a better protection than a second dose of Covishield vaccine administered after 4 weeks. It is admitted in the statement filed on behalf of the Central Government that the immunity provided by the second dose of Covishield vaccine with time interval less than 12-16 weeks would be better than partial vaccination namely single dose. According to the petitioners, in a country like India, where a substantial part of the population is yet to be vaccinated and where large number of persons are infected with Covid -19 on a day-to-day basis and where the infection is leading to casualty in large number of cases, the need of the hour is not better protection or best protection, but early protection from infection. In other words, as indicated at the outset, what the petitioners claim is a right to make a choice on behalf of their workers, between early protection and better protection from Covid–19 infection in the matter of accepting vaccine. It is also the case of the petitioners that at any rate, the people should certainly have a right to exercise a choice between early protection and better protection in the matter of accepting paid vaccine.

- 8. The principle that every human-being of adult years and sound mind has a right to determine what shall be done with his/her body, though not of Indian origin, has been widely accepted by the courts in India. It appears, it is in recognition of the said principle that the vaccination for Covid-19 is made voluntary. The fact that the vaccination is voluntary and there is no compulsion on anyone to accept the same is declared by the Government of India in the website of the Ministry of Health and Family Welfare. If that be so, the requirement to administer two doses of the vaccine and the time interval between the two doses for better protection from infection can only be considered as advisory. In other words, as pointed out by the petitioners, when the people have even the right to refuse to accept vaccine, there is absolutely no reason why the State should take the stand that they shall not be permitted to accept the second dose, if they choose to do so after four weeks in terms of the original protocol of the vaccine for their early protection, especially when they themselves are procuring the vaccine by spending money from their pockets. It is all the more so since the policy of the Central Government itself is, as discernible from the website of the Ministry of Health and Family Welfare, that the people shall have the choice to get early vaccination, for the implementation of which vaccine is being distributed on payment of its cost through private hospitals as well. True, exercise of such a right by individuals cannot be said to be absolute and the same is subject to the rights of others, in the instant case, the fundamental right under Article 21 of the Constitution, viz, the right to health. In other words, it is open to the Government to treat such categories of persons as a class different from persons who have accepted vaccine in terms of its protocol, in the matter of imposing restrictions or relaxing restrictions, as the case may be, to contain the spread of the pandemic.
- 9. That apart, the materials on record indicate that the Central Government has relaxed the time interval between the two doses of the Covishield vaccine initially, for students who have to undertake foreign travel for the purpose of education, for persons who have to take up jobs in foreign countries, and for athletes, sports persons and accompanying staff of Indian contingent attending the

Olympic Games at Tokyo. The materials also indicate that the said privilege was extended to Indian Government officials mandated to attend official commitments abroad. The privilege was extended again later to those individuals who have to travel abroad for other purposes such as for availing treatment services for any health problems, foreign nationals who have to return to their native countries or to any other circumstances where such foreign travel may be unavoidable. Similarly, the State Government on its own, without the concurrence of the Central Government, has relaxed the time interval between the two doses of the Covishield vaccine to those who intend to go abroad for employment. These facts are not in dispute. In other words, the Government have permitted all those classes of persons to exercise the choice between early protection and better protection from Covid-19 infection. All those are not persons who reside and settle permanently abroad. Most of them are persons who have to come back to India soon after their assignment. If the Government can permit persons who are intending to travel abroad to exercise a choice between early protection and better protection from Covid-19 infection, there is absolutely no reason why the same privilege shall not be extended to others who want early protection in connection with their employment, education, etc. Further, the stand taken by the Central Government that the court shall not grant the relief sought for by the petitioners, for they have not approached the Central Government, cannot be accepted, for, as indicated, the very premise on which the present writ petition is instituted is that the decision of the Government in providing relaxation in the protocol regarding administration of second dose of vaccine to certain classes of persons alone amounts to discrimination and the directions sought are directions to extend to the petitioners also the same relief. In cases of this nature, according to me, the relief sought by the petitioners cannot be denied merely for the reason that the petitioners have not approached the Government for the same.

In the result, the writ petition is allowed and the fourth respondent is directed to make necessary provisions forthwith in the CoWIN portal, so as to enable scheduling of second dose of Covishield vaccine after four weeks of

the first dose for those who want to accept the second dose after a period of four weeks in terms of the initial protocol of the vaccine. It is, however, made clear that I have not considered the question whether a person is entitled to make a choice between early protection and better protection from Covid—19 infection in the matter of accepting the free vaccine provided by the Government."

2. Facts leading to the filing of instant writ appeal are as under:

W.P.(C) No.16501 of 2021 was filed by respondents 1 & 2 herein. In order to improve the immunity, health and well-being of their employees, and to ensure timely export shipments, adhering to Government protocol, the respondents/writ petitioners, which are private limited companies, purchased and administered the first dose of COVISHIELD vaccine to all their employees and family members, in June, 2021.

Thereafter, respondents 1 and 2 again purchased 12000 doses of COVISHIELD vaccine from a hospital at Muvattupuzha, at their own expenses, to administer the second dose to their employees. According to the writ petitioners, majority of their employees have completed 40 days after the first dose.

Writ petitioners have further stated that previously the gap required between two doses of COVISHIELD vaccine was minimum 4 to 6 weeks. Thereafter, it was increased to 45 days and further to 84 days,

considering the availability of vaccine. As per the current protocol, Covid portal (CoWIN) does not permit administration of the 2<sup>nd</sup> dose of COVISHIELD vaccine, within a period of not less than 84 days.

Writ petitioners have further stated that the National Health Mission has issued a circular dated 29.05.2021 (Exhibit-P1) fixing guidelines to assist the implementation of vaccination. Pursuant to Exhibit-P1 circular, State of Kerala, represented by the Principal Secretary, Health and Family Welfare Department, Thiruvananthapuram, respondent No.3 has also issued G.O.(Rt.) No.1155/2021/H&FWD dated 28.05.2021 (Exhibit-P2), fixing guidelines for vaccination. As per the said guidelines, a person, who took the first dose of COVISHIELD vaccine and wants to get travel clearance for travelling abroad, shall be eligible for second dose, after four to six weeks' interval of administering the first dose of vaccine and relaxation is given to such persons, who intend to travel abroad with travel documents.

Being aggrieved, writ petitioners approached the 3<sup>rd</sup> respondent - State, by filing representations dated 23.07.2021 and 07.08.2021 (Exhibits-P3 & P4) respectively, requesting to relax the duration of the second dose of COVISHIELD vaccine and sought for permission to administer the same to their employees, who have completed 4 to 6

weeks, after the first dose of vaccine.

Alleging non-consideration of the representation by the State of Kerala, writ petition was filed seeking for a writ of mandamus commanding the State Health Authorities/respondents to accord sanction to the writ petitioners, to administer the second dose of vaccine to their employees and family, who have completed four to six weeks after the first dose, at their own cost.

- 3. Before the writ court, respondents 1 & 2/writ petitioners, have contended that domestic labour and their protection to the health and life of workers are also a fundamental right guaranteed under Articles 14 and 21 of the Constitution of India and its directive policies, and that, any interpretation to differentiate travel or employment and domestic employment, in the matter of vaccination and relaxation to one category alone, would result in discrimination.
- 4. It is the contention of the appellant that during the course of hearing, on behalf of the State of Kerala, it was submitted that the interval between two doses cannot be relaxed, as the same would go against the National Vaccine Policy of the Government of India. Thereupon, the learned Single Judge *suo motu* impleaded the appellant.
  - 5. Subsequently, a detailed statement was filed by the appellant/

4<sup>th</sup> respondent before the writ court, explaining the vaccine policy of the Government of India. Relevant portions of the said statement are extracted hereunder:

- Α. The National Technical Advisory Group of Immunization (NTAGI) was established by an order of the Ministry of Health and Family Welfare (MoHFW), in 2001. As India's Apex Advisory body on immunization, NTAGI provides guidance and advice to the MoHFW on the provision of vaccination and immunization services for the effective control of vaccine preventable diseases in the country.
- B. It was further contended that the dose interval between the two doses of COVISHIELD vaccine under the COVID-19 vaccination drive has undergone a series of revision based on the available and emerging scientific evidence with overall quidance of the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC). Presently, based on recommendations by NEGVAC, the schedule of COVISHIELD vaccine under National COVID-19 Vaccination Program is to administer the 2<sup>nd</sup> dose at 12-16 weeks' interval (i.e., after 84 days), after administration of the first dose. This is based on the technical opinion that the duration of 84 days between 1<sup>st</sup> and 2<sup>nd</sup> doses of COVISHIELD is providing best protection against COVID-19. However, with a view to provide full vaccination coverage and facilitate

international travel for genuine reasons, it was decided to allow the 2<sup>nd</sup> dose before the prescribed time period of 12-16 weeks. As per the evidence available, the immunity provided by two doses of COVISHIELD vaccine with interval less than 12-16 weeks would be better than partial vaccination (single dose).

- C. Referring to Annexure-R4(a) letter from the Ministry for Administration dated 7.6.2021, appellant has contended before the writ court that the matter was discussed in the Empowered Group 5 (EG-5) and appropriate recommendations were obtained. In that context, with a view to provide full coverage of vaccination and facilitate international travel for such genuine reasons, directions along with SOP were issued by the Ministry for administration of second dose of COVISHIELD vaccine, prior to the prescribed time interval (after 28 days, but before 84 days) for the following beneficiaries:
  - (i) Students who have to undertake foreign travel, for the purposes of education.
  - (ii) Persons who have to take up jobs in foreign countries.
  - (iii) Athletes, sports persons and accompanying staff of India contingent attending the International Olympic Games to be held in Tokyo.
- D. It was further contended that pursuant to the above said directions, on 9.7.2021, the relaxation for getting second dose of COVISHIELD vaccine prior to the

- prescribed interval of 84 days was further extended to Indian Government officials, who are mandated to attend official commitments abroad.
- E. It was also submitted that the decision to increase the dose interval of COVISHIELD vaccine was based on scientific evidences and expert opinion as per available efficacy data.
- 6. After considering the rival submissions, by the impugned judgment, writ court allowed the writ petition and directed the 4<sup>th</sup> respondent to make necessary provisions forthwith in the CoWIN portal, so as to enable scheduling of second dose of Covishield vaccine, after four weeks of the first dose, for those, who want to accept the second dose, after a period of four weeks, in terms of the initial protocol of the vaccine. It was, however, made clear in the impugned judgment that the writ court has not considered the question, as to whether a person is entitled to make a choice between early protection and better protection from COVID–19 infection, in the matter of accepting the free vaccine provided by the Government.
- 7. Being aggrieved, instant writ appeal is filed by the appellant on the following grounds:
  - A. Learned Single Judge ought to have dismissed the Writ Petition as not maintainable on the ground that the writ

petitioners never approached the Central Government/ appellant to relax the duration of the 2<sup>nd</sup> dose of COVISHIELD vaccine and sought permission to administer the same to their employees, who have completed 4-6 weeks after the 1<sup>st</sup> dose of vaccine.

- B. Learned Single Judge ought not have interfered with the vaccine policy of the Government of India. The National Vaccine Policy is formulated based on the opinions and advice of Experts in the field and also based on clinical trials. Hence any change in the policy can only be carried out based on the necessary approvals and clinical trials. The judgment of the learned Single Judge would derail the vaccination policy throughout the country.
- C. Learned Single Judge ought to have seen that India's National COVID Vaccination Program is built on scientific and epidemiological evidence, WHO guidelines and global best practices. Hence, the writ court should not have substituted its wisdom and relaxed the conditions stipulated by the Expert Bodies.
- D. Learned Single Judge failed to consider the fact that the dose interval between two doses of COVISHIELD vaccine under COVID-19 vaccination drive has undergone a series of revision based on the available & emerging scientific evidence mentioned above with overall guidance of the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC). Presently, based on the recommendations by NEGVAC, schedule of COVISHIELD

vaccine under National Covid-19 Vaccination Program is to administer the  $2^{nd}$  dose at 12-16 weeks' interval (i.e., after 84 days), after administration of  $1^{st}$  dose. This is based on the technical opinion that the duration of 84 days between  $1^{st}$  and  $2^{nd}$  doses of COVISHIELD is providing best protection against COVID-19.

- E. Learned Single Judge failed to consider the fact that National COVID-19 Vaccination Program is the largest COVID-19 vaccination program of its kind in the world. This program is under a constant and systematic review to take into account emerging scientific evidence, vaccine availability, experience on the ground and global best practices.
- F. Learned Single Judge failed to consider the fact the Vaccine program is being guided by science and domain knowledge experts through a National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) which provides guidance on all aspects of COVID-19 vaccination including prioritization of population groups, procurement and inventory management, vaccine selection, vaccine delivery and tracking mechanism etc. The NEGVAC comprises of subject matter experts, secretaries of all pertinent Ministries of Government of India, eminent technical experts and State Governments representatives, for evidence based and collaborative decision making that is adaptive to local needs. It provides guidance on all aspects of the COVID-19 vaccine introduction in India including regulatory guidance on vaccine trials, vaccine

- selection, equitable distribution of vaccine, procurement, financing, delivery mechanisms, prioritization of population groups, vaccine safety surveillance etc.
- G. Learned Single Judge ought to have considered that relaxation has been offered in favour of persons forming a separate class by themselves, classified for valid reasons and hence the petitioners or the beneficiaries claiming through the writ petitioners cannot claim parity with a different but distinct class in the matter of interval in administration of vaccine doses. Hence, no relaxation has been granted to any other person by the Ministry of Health & Family Welfare, New Delhi.
- H. Learned Single Judge ought to have noticed that as a part of the strategy to contain the pandemic, the Government of India have devised a policy based on scientific studies which is being reviewed after studies. Hence, it is the responsibility of the Government to ensure that all eligible citizens of the country are administered with the vaccine subject to other necessary restrictions and this would be possible only on adopting judicious administration policy. Under the fanciful guise of earlier protection claimed by the writ petitioners, if large quantities of vaccine doses are administered prematurely, the same would not only amount to inappropriate administration but also would affect the prospects of the remaining population waiting for their turn of vaccine. Hence, the mechanism devised by the Government ought not have been interfered with by the court.

- I. Learned Single Judge ought to have seen that if the Government is forced to honour the claims of other groups or industrial units like the writ petitioners the same would have cascading adverse effects, on the organised and regulated pattern of vaccine administration.
- J. Learned Single Judge failed to observe that even according to the writ petitioners, an interval between 12 weeks to 16 weeks is most effective. Under such circumstances, it would not be proper in the public interest to concede for a shorter interval under the fanciful guise of earlier protection.
- K. The very approach of the learned Single Judge trying to adopt a comparison between an unrealistic notion of earlier protection and the realistic element of better protection was faulty and would lead to serious adverse consequences in the larger public interest. This is especially since nothing is brought out to suggest that an interval of 12 weeks for the second dose of vaccine would deny any effective protection to a person taking vaccination. The concept of 12 weeks interval, which is based on scientific study, meant that better immunity on the strength of the first vaccine would be available only by 12 weeks and not before. Hence, any insistence to avail the second dose of vaccine prior to 12 weeks, actually will impede the development of immunity.
- L. The judgment of the learned Single Judge thereby attempting to evaluate an issue which is to be viewed in a

- scientific angle, more as an issue, falling under Art. 14 of the Constitution of India, would result in a social disaster which should not be allowed to happen.
- M. Learned Single Judge ought not have entertained the Writ Petition in respect of a matter which squarely fell under the State policy, otherwise supported with valid scientific studies. The learned Single Judge went wrong in finding that the Government have permitted those classes of persons to exercise the choice between early protection and better protection from COVID-19.
- N. The judgment of the learned Single Judge would work out a serious disorder in the implementation of the national strategy of Union Government to fight COVID-19, and therefore, liable to be set aside. By permitting individuals to opt for paid vaccination for early protection, in connection with their employment, education, etc., this Court itself drawn a classification between individuals.
- 8. Mr. P. Vijayakumar, learned Assistant Solicitor General of India, submitted that though the time gap required between two doses of COVISHIELD vaccine was 4 to 6 weeks, thereafter, it was increased to 45 days and further to 84 days, considering the studies made by the National Technical Advisory Group on Immunization (NTAGI) and National Expert Group on Vaccine Administration for Covid-19 (NEGVAC). Therefore, according to the learned ASGI, the submission made by the

writ petitioners that the interval of vaccine has been increased to 84 days, due to the non-availability of vaccine, can never be sustained, especially due to the fact that Union of India relied on the expert scientific reports and studies of the competent authority.

- 9. Learned Assistant Solicitor General further submitted that as per the current protocol, CoWIN Portal does not provide for administering the 2<sup>nd</sup> dose of COVISHIELD vaccine, within a period of not less than 84 days. He submitted that the interval of 84 days for the 2<sup>nd</sup> dose was not based on any executive decision, but on the basis of a clear scientific advice and that the relaxation has been given by the Government as per requirement of a particular class of persons, who are to go abroad for studies, treatment, employment requirements, and for participation in the Olympic games. According to the learned ASGI, the relaxation provided for administering the 2<sup>nd</sup> dose of COVISHIELD vaccine was based on *intelligible differentia* and it is a reasonable classification.
- 10. Learned ASGI further invited the attention of this Court to Annexure-I minutes of the meeting of Standing Technical Sub Committee of NTAGI dated 13.05.2021, produced along with the writ appeal, wherein Agenda I is in relation to update of the COVID-19 Working Group, which reads thus:

### "Agenda 1: An Update of the COVID-19 Working Group: Dr. N. K. Arora

Dr. N. K. Arora presented a brief timeline of activities of the COVID-19 working group. Further the committee was appraised with WG deliberations in past 5 meetings: (i) Clinical Trial Data of COVAXIN and Sputnik V vaccines, (ii) Progression of second wave of Covid-19 pandemic in India and COVID-19 vaccine safety surveillance data in India, (iii) Dosing interval between two doses of Covishield Vaccine, (iv) Definition and Duration of Protection from Reinfection of SARS-CoV2, (v) COVID-19 Vaccine durina pregnancy & lactation, Contraindications and Precautions related to COVID-19 Vaccines, (vii) Rapid Antigen Testing prior to COVID-19 vaccination, (vii) Blood donation after vaccination, (viii) Travel Quarantine of COVID-19 vaccinated persons.

- It was informed that a presentation was made in NEGVAC on behalf of the COVID-19 WG on May 12, 2021 and based on the feedback additional information was added in the presentation.
- In the last one month, five meetings, COVID-19
  WG feel very honoured that the amount of
  confidence NTAGI has in it. In the last one
  month several policy questions were assigned to
  deliberate on.
- Between February 01, 2021 to March 01, 2021, there was not much difference in the number of new cases, but from there it started taking off four times in four weeks, and then again four-six times in next four weeks. Cumulative daily growth rate from first March 01, 2021 to May 01, 2021 was 7-8%.
- At the moment there is a severe shortage of the vaccines, particularly after the government announced the vaccination of the 18 to 45 years old age group, this has further escalated the shortage.
- In January, 2021, COVID-19 vaccination program started with a four-week interval between first and second dose of Covishield. Six

weeks later, NTAGI-STSC revisited the interval between two doses of Covishield when WHO-SAGE interim recommendations on AZD1222/ Covishield was published with an 8-12 weeks interval between two doses. All that time there was a particular concern of breakthrough infection between first and second dose, and level of protection offered on extension of doses, the initial trial data was showing protection. Considering the concerns, at that time, an interval of six to eight weeks was recommended with suggestion of close monitoring on new evidence along with suggested research studies.

- Last week this issue was given to COVID-19 WG again, data was reviewed, now new real-life data has come up, particularly UK particularly. Although there are some other countries in South-East Asia region, like Bangladesh and Sri Lanka, who are using more than eight weeks or 10 weeks of interval between two doses of Covishield. EMA has recommended an interval of 4-12 weeks. Spain and Canada recommended an interval of 4 months between two doses of AZD1222 vaccine. There are three studies from UK which have shown anywhere between 65% to 80% protection rate after the first dose, if the interval is up to 12 weeks and this is real life data.
- It is very important to understand that the Public Health Agency of England went in for an expanded interval between the doses not only because there was some evidence from the data for Astra Zeneca. But even they expanded the interval of Pfizer vaccine as well in order to cover maximum people. New evidence shows that even with Pfizer, it seems to be 65% protection with the first dose, and post second dose protection was just 70%.
- Covaxin data suggests that after first dose seroconversion around 38% and, therefore, it is

- suggested that its interval should not be increased.
- A second dose of Covishield may be administered beyond 16 weeks, may be six months or later. But this requires evidence and that the manufacturer may be asked to lead this exercise and there can be facilitation from the system.
- 11. Relying on the decision of the advisory group, learned ASGI further submitted that there was a clear scientific data available, in order to take a decision to administer the 2<sup>nd</sup> dose of vaccine, within 8-12 weeks interval and it was accordingly, the minimum interval of 84 days was fixed, and therefore, the contention advanced by the writ petitioners that the notifications/orders issued by the Union Government are without any basis, cannot be sustained.
- 12. Learned ASGI further submitted that the efficacy of the vaccine would be higher or better after 84 days, which is an admitted fact by the writ petitioners themselves. However, the writ petitioners claimed that they want an early protection of their employees rather than better protection, which is their fundamental right.
- 13. Learned ASGI also submitted that though in the statement filed before the writ court, the reason for administering the vaccine after 84 days was put forth, learned Single Judge has not taken into account the

scientific and technical aspects of the matter, however, proceeded on the basis that the writ petitioners have a fundamental right to seek for an early protection of its employees.

- 14. That apart, it was contended that the theory of better protection was found out by the scientists and experts in the field, in order to have better protection of the people at large, taking into account the public interest, and therefore, the contention advanced by the writ petitioners that interest of their employees should be protected early cannot be given any credence considering the larger public interest.
- 15. It was also submitted that Union Government is vested with ample powers under the provisions of the Disaster Management Act, 2005, to impose reasonable conditions, so far as administration of vaccine is concerned, taking note of the safety precautions that are to be made, in order to protect life and liberty of the people at large. Therefore, according to the learned ASGI, there is no scope for advancing an argument that a particular group of citizens employed with the writ petitioners have to be given preference, overlooking the time interval envisaged by the Union Government.
- 16. Learned ASGI further submitted that learned Single Judge was not right in substituting the scientific findings of the competent body

advising the Central Government, in order to have a regulated activity of administering the vaccine in the better interest of the nation as such.

17. Learned ASGI invited attention of this Court again to Annexure-I minutes dated 13.05.2021, of the NTAGI, in particular, the recommendations of the meeting, which reads as under:

#### "Recommendations made by the COVID-19 WG:

Dosing interval of AZD1222/Covishield vaccine:

- Based on the available real-life evidences particularly from UK, the COVID-19 working group agreed for increasing the dosing interval to 12-16 weeks between two doses of Covishield vaccine.
- No change in interval of COVAXIN vaccine doses was recommended.
- The COVID-19 WG strongly recommended to urgently establish a national vaccine tracking platform to determine the impact of the COVID-19 vaccine (s) and the breakthrough infections that are likely to occur among those with complete and partial immunization. The vaccine tracker will be particularly important to monitor the impact of increasing the dosing schedule of COVISHIELD. The current data harmonization work of ICMR and other agencies to be leveraged to set up this facility for review of the ground realities on a real time basis.
- To consider varying dosing intervals including a

single dose of COVISHIELD in program setting, studies should be initiated using novel methods, including RCT built into vaccine delivery systems.

- 18. Learned ASGI also invited our attention to the various decisions of the Hon'ble Supreme Court, in order to canvas the proposition that a reasonable classification made to provide vaccine to a particular group going abroad can never be treated as an arbitrary exercise of power and an unreasonable classification.
- Murthy Match Works and Others v. Asst. Collector of Central Excise and Others [(1974) 4 SCC 428], learned ASGI submitted that classification can be sustained only if it is founded on pertinent and real difference, as distinguished from irrelevant and artificial ones; that if it rests on a difference, which bears a fair and just relation to the object for which it is proposed, it is constitutional; to put it differently, the means must have nexus with the ends; even so, a large latitude is allowed to the State for classification upon a reasonable basis and what is reasonable is a question of practical details and a variety of factors, which the Court will be reluctant and perhaps ill equipped to investigate. It was further held in the said decision that the question of classification

is primarily for legislative judgment and ordinarily does not become a judicial question and that a power to classify being extremely brought and based on diverse considerations of executive pragmatism, and judicature cannot rush in where even the legislature warily treads.

20. Learned Assistant Solicitor General of India further submitted that when a policy is supported by valid consideration, especially with scientific reports, Courts will be very slow in interfering with those matters. In support of the said contention, learned ASGI has relied on the decision in **Union of India and Others** v. **S. L. Dutta and Another** [(1991) 1 SCC 505], in particular, paragraphs 9, 10, 11, 15 and 16. He laid emphasis on paragraph (16) of the said decision, wherein the Hon'ble Apex Court observed thus:

"16. Mr. Datar, learned counsel for respondent No. 1 did not dispute that, normally, it was not for the court to consider the wisdom or appropriateness of a particular policy, particularly in cases where expert knowledge was required in the formulation of the policy and considering the appropriateness of the policy. It was, however, submitted by him that once a policy was settled the Government was bound to follow that policy and that, if the policy had to be changed, this could be done only on a proper consideration of the relevant material and could not be resorted to for ulterior purposes or mala fide nor could

the policy be changed arbitrarily. He placed reliance on the judgment of this Court in case of A. S. Sangwan (AIR 1981 SC 14 ), discussed earlier. What is, however, significant is that in that very judgment this Court held (See para 4 of the aforesaid Report) that a policy once formulated is not good for ever; it is perfectly within the competence of the Union of India to change it, rechange it, adjust it and readjust it according to the compulsions of circumstances and the imperatives of national considerations. That judgment, therefore, is of no avail to the appellant."

- 21. Learned ASGI further relied on the decision in **Vincent Panikulangara** v. **Union of India and Others** [(1987) 2 SCC 165], wherein the Hon'ble Supreme Court had an occasion to consider the question of banning import, manufacture, sale and distribution of certain drugs and held that the Central Government, on the basis of the expert advice, can indeed adopt an approved national policy and prescribe adequate number of formulations, which would on the whole, meet the requirement of the people at large.
- 22. Learned ASGI further relied on the decision in **Prabhakaran**Nair v. **State of T.N. And Others** [(1987) 4 SCC 238], wherein the Hon'ble Apex Court had an occasion to consider the question of classification in the realm of Rent Control legislation, and, at paragraph 28, held as under:

"28. Courts are not concerned with the unwisdom of legislation. "In short, unconstitutionality and not unwisdom of a legislation is the narrow area of judicial review." See in this connection the observations of Krishna Iyer, J. in Murthy Match Works v. The Asstt. Collector of Central Excise, [1974 (3) SCR 121 : AIR 1974 SC 497]. This Court approved the above passage from the American Jurisprudence and emphasised that in a classification for governmental purposes there cannot be an exact exclusion or inclusion of persons and things. It is important to bear in mind the constitutional command for a State to afford equal protection of the law sets a goal not attainable by the invention and application of a precise formula. Therefore, a large latitude is allowed to the States for classification upon any reasonable basis. See also in this connection the observations of this Court In re The **Special Courts Bill, 1978**, [1979 (2) SCR 476 : AIR 1979 SC 478], where Chandrachud, C. J. speaking for the Court at pages 534 to 537 of the report laid down the propositions guiding Art. 14 and emphasised that the classification need not be constituted by an exact or scientific exclusion nor insist on delusive exactness or apply doctrinaire tests for determining the validity of classification in any given case. Classification, therefore, is justified if it is not palpably arbitrary. We also in view of the different provisions we have discussed bear in mind the fact that there is no such consensus among the different States about the right of re-induction of tenant in case of eviction

required for demolition. It will depend on the particular State and, appreciation of the need and problem at a particular point of time by that State concerned. The purpose underlying S.14(1)(b) read with S.16(2) of the Tamil Nadu Rent Act, is to remove or mitigate the disinclination on the part of landlords to expend moneys for demolition of dilapidated buildings and reconstruct new buildings in their places. It is a matter of which, judicial notice can be taken that the return from old and dilapidated buildings is very meagre and in several cases such buildings prove uneconomic for the landlords with the result that the condition of the building deteriorates and there are even collapses of such buildings. It is for this purpose that the landlord is given by S.14(1)(b) read with S.16 an incentive in the form of exemption from the provisions of the Rent Act in respect of reconstructed building for the limited and short duration of five years...."

and Others v. Chairman Central Bd. of Dirs., SBI and Another [(2002) 2 SCC 259], wherein the Hon'ble Apex Court had an occasion to consider the question of classification, in terms of Article 14 of the Constitution of India, in the matter of terms and conditions of service of the officers of State Bank of India, and held as follows:

"Before we deal with the respective contentions of the parties it would be appropriate for us to notice that what

Art.14 prohibits is class legislation and not reasonable classification for the purpose of legislation. If the rule Making Authority takes care to reasonably classify persons for a particular purpose and if it deals equally with all persons belonging to a well defined class then it would not be open to the charge of discrimination. But to pass the test of permissible classification two conditions must be fulfilled:-

- (a) that the classification must be founded on an intelligible differentia which distinguishes persons or things which are grouped together from others left out of the group; and
- (b) that the differentia must have a rational relation to the object sought to be achieved by the statute in question.

The classification may be founded on a different basis and what is necessary is that there must be a nexus between the basis of classification and the object under consideration. Art.14 of the Constitution does not insist that the classification should be scientifically perfect and a Court would not interfere unless the alleged classification results in apparent inequality. When a law is challenged to be discriminatory essentially on the ground that it denies equal treatment or protection, the question for determination by Court is not whether it has resulted in inequality but whether there is some difference which bears a just and reasonable relation to the object of legislation. Mere differentiation does not per se amount to discrimination within the inhibition of the equal protection clause. To attract the operation of the clause it is necessary to show that the selection or differentiation is unreasonable or arbitrary; that it does not rest on any rational basis having regard to the object which the legislature has in view. If a law deals with members of well defined class then it is not obnoxious and it is not open to the charge of denial of equal protection on the ground that it has no application to other persons. It is for the Rule Making Authority to determine what categories of persons would embrace within the scope of the rule and merely because some categories which would stand on the same footing as those which are covered by the rule are left out would not render the Rule or the Law enacted in any manner

discriminatory and violative of Art.14. It is not possible to exhaust the circumstances or criteria which may afford a reasonable basis for classification in all cases. It depends on the object of the legislation, and what it really seeks to achieve."

24. In **A.S. Sangwan** v. **Union of India (UOI) and Ors**. (AIR 1981 SC 1545), the Hon'ble Supreme Court had an occasion to consider the question of reasonable classification and held as under:

"4. The policy statement of 1964 was, as we have earlier stated, not issued under any rules or regulations or statute. The executive power of the Union of India, when it is not trammelled by any statute or rule, is wide and pursuant to its power it can make executive policy. Indeed, in the strategic and sensitive area of defence, Courts should be cautious although Courts are not powerless. The Union of India having framed a policy relieved itself of the charge of acting capriciously or arbitrarily or in response to any ulterior considerations so long as it pursued a consistent policy. Probably, the principle of equality which interdicts arbitrariness promoted the Central Government to formulate its policy in 1964. A policy once formulated is not good for ever, it is perfectly within the competence of the Union of India to change it, rechange it, adjust it and re-adjust it according to the compulsions of circumstances and the imperatives of national considerations. We cannot, as Court give directives as to how the Defence Ministry should function except to state that the obligation not to act arbitrarily and to treat employees equally is binding on the Union of India because it functions under the Constitution and not over it. In this view, we agree with the submission of the Union of India that there is no bar to its changing the policy formulated in 1964 if there are good and weightly reasons for doing so. We are far from suggesting that a new policy should be made merely because of the lapse of time, nor are we inclined to suggest the manner in which such a policy should be shaped. It is entirely within the reasonable discretion of the Union of India. It may stick to the earlier policy or I give it up. But one imperative of the

Constitution implicit in Article 14 is that if it does change its policy, it must do so fairly and should not give the impression that it is acting by any ulterior criteria or arbitrarily. This object is achieved if the new policy, assuming Government wants to frame a new policy, is made the same way in which the 1964 policy was made and not only made but made known. After all, what is done in secret is often suspected of being capricious or mala fide. So, whatever policy is made should be done fairly and made known to those concerned. So, we make it clear that while the Central Government is beyond the forbiddance of the Court from making or changing its policy in regard to the Directorate of Military Farms or in the choice or promotion of Brigadiers, it has to act fairly as every administrative act must be done."

- 25. Learned ASGI further submitted that the two limbs on which the judgment would stand otherwise are rendered ineffective. For the sake of completeness, learned ASGI referred to paragraphs 9, 10, 11, 12 & 14 of the writ appeal and grounds (b), (f), (h), (i) & J, wherein the appellant has explained the rationale. He also submitted the very premise on which the writ petition is founded that it was due to shortage in the production of vaccine, a higher duration given is shattered, because, in the case of Covaxin, still the period of one month is maintained. If that be so, learned ASGI submitted, then as regards Covaxin, time duration would be three or four months.
- 26. Learned ASGI further submitted that writ petitioners have no case that any of their statutory right is violated; by an inferential context,

they seek to submit that since adults going abroad are given relaxation, the writ petitioners are not given the same; though the learned single Judge did not refer to Article 14 of the Constitution of India, it was found that since privilege is given to those who are going abroad, it shall also be extended to the writ petitioners, which, according to the appellant, shall not be done, because those who are going abroad, form a class by themselves on valid grounds, while the writ petitioners are locally available citizens, who should have their own time, and to be given better protection, not the early protection.

27. He further submitted that the vaccine is not a private property. No doubt, it is a privilege or protection that has to be administered in a regulated manner. Partly, still it is a Government property, since the Government is funding the manufacturer companies with the larger objective of securing the interest and health of the people. Hence, Government have two aspects; firstly, the maximum number of people should be given the best protection and secondly, to ensure such protection to the maximum number of people in the best way, there should be a regulatory mechanism and that is why vaccines are still not made available in medical shops. It is dispensed only through hospitals, where they are administering vaccines. Nobody is given a vaccine on

hand. It is not a chattel that can be carried from the hospital after paying money. No doubt, the writ petitioners have paid the amount. But, the vaccine is to be administered through the CoWIN Portal as per the standard norms. According to the learned ASGI, that cannot be jettisoned or that cannot be jeopardized.

28. Now, the other anomalous reasoning pointed out by the learned ASGI for the appellant is that early protection or better protection is not all a proper consideration for adjudication of the issue. They want the best possible available protection. That cannot be a mere protection because, only after a period of 84 days, there would be the best protection. Hence, after administering the first dose of vaccine, persons have to wait for 84 days, then only the second dose of the vaccine would be most effective. Viewed from that angle, administration of a second dose of vaccine before 84 days' duration is a waste of vaccine, in order to get best protection. Nobody can say, I want the second dose of vaccine on the second day after the first dose. He also submitted that vaccines are a national property, which has to be administered in a judicious manner, to ensure the best protection to the entire population, not to a handful of workers in a particular factory. Hence, actually by filing the writ petition, granting the reliefs sought for

by the writ petitioners would amount to putting spanner in the box of administration causing great national calamity.

- 29. Learned ASGI for the appellant further submitted that though writ petitioners claim that they have procured vaccine by spending huge amounts, the vaccine is still stored in hospitals in the required climatic conditions. Hence, the available vaccine should be administered in the best way and that giving vaccination before the due duration would render the administered vaccination waste and the writ petitioners are not benefited by the early vaccination.
- 31. On the other hand, he also submitted that those who are genuinely waiting for 84 days, their privilege will be, of course, deprived off or party affected, because the writ petitioners, in bulk, procure the vaccine in advance, without getting the efficacious result. For the purpose of protecting a very limited number of persons, whether this is a well ordained machinery or whether this should be affected or interfered with through a judgment.
- 32. Learned ASGI further submitted that if the writ petition is allowed, then all the companies, who are able to provide vaccines to their employees, will approach this Court and the 25% would be exhausted and it would become a bad precedent. He finally submitted

that the entire basis on which the impugned judgment is founded, is based on two legs. Firstly, it is a private property, which is wrong. Secondly, it is to be given as in the case of those persons who are going abroad, is also fallacious.

- 32. Mr. V. Manu, learned Senior Government Pleader, submitted that State as an entity, supports the impugned judgment, insofar as that will augment the second dose of vaccination being administered in the State on early basis. Therefore, according to the learned Senior Government Pleader, it will be in the better interest of the State if, the impugned judgment is implemented by the Union Government.
- 33. *Per contra,* Mr. Blaze K. Jose, learned counsel for the writ petitioners/respondents 1 & 2, submitted that even though vaccine/ medical protocol allows to have the second dose of vaccine, after 28 days, Government have restricted from taking the second dose before 84 days, for the reason that the said interval provides the best efficacy and, therefore, the individual is prevented from having a choice of early protection of life, by taking paid vaccines, which comes under fundamental right to life guaranteed under Article 21 of the Constitution.
- 34. Learned counsel for the writ petitioners further submitted that the vaccine is voluntary and not compulsory, and therefore, the

fundamental right to life and liberty allows an individual to decide when he should take the vaccine or not and be protected. He also contended that it is the extension of the said right to decide when or at what time, a citizen needs protection and when a citizen should take the second dose as per the vaccine protocol, especially in a situation where vaccine/medical protocol allows to have the 2<sup>nd</sup> dose of vaccine in between 28 days and 12-16 weeks.

- 35. Learned counsel for the writ petitioners also contended that the State can impose some restrictions, but not absolute restriction from taking the vaccine after 28 days and before 84 days, especially due to the fact that the vaccine protocol does not prohibit administration of vaccine after 28 days.
- 36. The point that the learned counsel for the writ petitioners attempted to impress upon us is that it is a personal choice of a citizen to decide as to whether he should take the vaccine before 84 days or after 84 days from the administration of the first dose of vaccine. It was also contended that since the administration of vaccine is not made compulsory by the Union Government, it is for the individual to decide as to whether he should go for an early protection before 84 days or better protection after 84 days. Therefore, learned counsel submitted that the

stand of the Union Government that the vaccine can only be administered after 84 days, by streamlining the CoWIN Portal accordingly, can never be sustained under law.

- 37. Apart from the above, learned counsel for the writ petitioners contended that the Union Government can only impose such restrictions on the free vaccines supplied by them and not on paid vaccines procured by individuals by paying directly to the manufacturer. Based on the above, it was forcefully contended that the restriction imposed is arbitrary and the authority has not followed the doctrine of proportionality before imposing such restrictions on the fundamental right of the individual to have the vaccine early, to protect life.
- 38. Learned counsel for the writ petitioners further contended that curtailment of fundamental rights without appropriate justification is disproportionate and that, the restriction should have been tailored in accordance with the stage, nature of urgency, exceptional medical situation, need for special groups, like doctors, nurses, health workers, etc. However, no relaxation is granted, except for people who are travelling abroad.
- 39. Above all, learned counsel for the writ petitioners contended that Government have neither disclosed before the citizens nor at least

before the Court, the efficacy of the first dose of vaccine or second dose, after 28 days, 45 days or 84 days, before coming to a decision to impose restrictions on 84 days for the second dose. So also, learned counsel for the writ petitioners submitted that the action is discriminatory, since the Government have decided to administer the second dose of vaccine before 84 days to persons, who undertake international travel for educational purposes, employment opportunities, medical treatment, athletes, sports persons and accompanying staff of the Olympic games, and that is not a reasonable classification making the decision of the Government to administer vaccine to such persons after 28 days and before completion of 84 days. To substantiate the said contention, learned counsel has submitted that the differentia so made does not distinguish persons or things grouped together not only from those who are left out of the group, but also similar persons like students, employees or people with comorbidities, who have to attend similar purposes, within the nation, is not granted with the relaxation.

40. Learned counsel for the writ petitioners further contended that there is no nexus between differently classified people and the object sought to be achieved by such relaxation or vaccination, since the sole reason put forth for relaxation is to enable the differently classified

people, to travel abroad or for entry into another country, which does not have any nexus with the object of vaccination or exemption.

- 41. He also contended that the appellant has miserably failed to affirmatively establish the twin tests, the *intelligible differentia* between the groups and the rational principle on which the classification is found correlated to the object sought to be achieved.
- 42. As regards the contention that the relaxation given by the Government is discriminatory and violative of Article 14 of the Constitution of India, learned counsel for the writ petitioners invited our attention to the decision of the Hon'ble Apex Court in **D.S. Nakara v. Union of India** reported in (1983) 1 SCC 305, wherein at paragraphs 11 to 16, it was held as under:
  - "11. The decisions clearly lay down that though Article 14 forbids class legislation, it does not forbid reasonable classification for the purpose of legislation. In order, however, to pass the test of permissible classification, two conditions must be fulfilled, viz., (i) that the classification must be founded on an intelligible differentia which distinguishes persons or things that are grouped together from those that are left out of the group; and (ii) that that differentia must have a rational relation to the objects sought to be achieved by the statute in question, (see **Shri Ram Krishna Dalmia v. Shri Justice S.R.**

**Tendolkar and Ors**. [1959]1SCR279). The classification may be founded on differential basis according to objects sought to be achieved but what is implicit in it is that there ought to be a nexus i.e., causal connection between the basis of classification and object of the statute under consideration. It is equally well settled by the decisions of this Court that Article 14 condemns discrimination not only by a substantive law but also by a law of procedure.

- 12. After an exhaustive review of almost all decisions bearing on the question of Article 14, this Court speaking through Chandrachud, C.J. in *Re. Special Courts Bill* [1979]2SCR476 restated the settled propositions which emerged from the judgments of this Court undoubtedly insofar as they were relevant to the decision on the points arising for consideration in that matter. Four of them are apt and relevant for the present purpose and may be extracted. They are:
  - "3. The constitutional command to the State to afford equal protection of its laws sets a goal not attainable by the invention and application of a precise formula. Therefore, classification need not be constituted by an exact or scientific exclusion or inclusion of persons or things. The Courts should not insist on delusive exactness or apply doctrinaire tests for determining the validity of classification in any given case. Classification is justified if it is not palpably arbitrary.
  - 4. The principle underlying the guarantee of Article 14 is not that the same rules of law should be applicable to all persons within the Indian territory or that the same remedies should be made available to them irrespective of differences of circumstances. It only means that all persons

similarly circumstanced shall be treated alike both in privileges conferred and liabilities imposed. Equal laws would have to be applied to all in the same situation, and there should be no discrimination between one person and another if as regards the subject matter of the legislation their position is substantially the same.

- 6. The law can make and set apart the classes according of the needs and exigencies of the society and as suggested by experience. It can recognise even degree of evil, but the classification should never be arbitrary, artificial or evasive.
- 7. The classification must not be arbitrary but must be rational, that is to say, it must not only be based on some qualities or characteristics which are to be found in all the persons grouped together and not in others who are left out but those qualities or characteristics must have a reasonable relation to the object of the legislation. In order to pass the test, two conditions must be fulfilled, namely, (1) that the classification must be founded on an intelligible differentia which distinguishes those that are grouped together from others and (2) that differentia must have a rational relation to the object sought to be achieved by the Act."
- 13. The other facet of Article 14 which must be remembered is that it eschews arbitrariness in any form. Article 14 has, therefore, not to be held identical with the doctrine of classification. As was noticed in *Maneka Gandhi's* case in the earliest stages of evolution of the Constitutional law, Article 14 came to be identified with the doctrine of classification because the view taken was that Article 14 forbids discrimination and there will be no discrimination where the classification making the

differentia fulfills the aforementioned two conditions. However, in **EP. Royappa v. State of Tamil Nadu** (1974)ILLJ172SC, it was held that the basic principle which informs both Articles 14 and 16 is equality and inhibition against discrimination. this Court further observed as under:

"From a positivistic point of view, equality is antithetic to arbitrariness. In fact, equality and arbitrariness are sworn enemies; one belongs to the rule of law in a republic while the other, to the whim and caprice of an absolute monarch. Where an act is arbitrary it is implicit in it that it is unequal both according to political logic and constitutional law and is, therefore, violative of Article 14, and if it affects any matter relating to public employment, it is also violative of Article 16. Articles 14 and 16 strike at arbitrariness in State action and ensure fairness and equality of treatment."

14. Justice Iyer has in his inimitable style dissected Article 14 as under:

"The article has a pervasive processual potency and versatile quality, equalitarian in its soul and allergic to discriminatory diktats. Equality is the antithesis of arbitrariness and *ex cathedra ipse dixit* is the ally of demagogic authoritarianism. Only knight-errants of 'executive excesses'-if we may use current cliche-can fall in love with the Dame of despotism, legislative or administrative. If this Court gives in here it gives up the ghost. And so it that I insist on the dynamics of limitations on fundamental freedoms as implying the rule of law; be you ever so high, the law is above you." [1978]2SCR621.

15. Affirming and explaining this view, the Constitution Bench in **Ajay Hasia etc. v. Khalid Mujib Sehravardi** and **Ors etc.** (1981)ILLJ103SC held that it must,

therefore, now be taken to be well settled that what Article 14 strikes at is arbitrariness because any action that is arbitrary must necessarily involve negation of equality. The Court made it explicit that where an act is arbitrary it is implicit in it that it is unequal both according to political logic and constitutional law and is, therefore, violative of Article 14. After a review of large number of decisions bearing on the subject, in **Air India etc. v. Nargesh Meerza and Ors. etc.** (1981)IILLJ314SC, the Court formulated propositions emerging from analysis and examination of earlier decisions. One such proposition held well established is that Article 14 is certainly attracted where equals are treated differently without any reasonable basis.

- 16. Thus the fundamental principle is that Article 14 forbids class legislation but permits reasonable classification for the purpose of legislation which classification must satisfy the twin tests of classification being founded on an intelligible differentia which distinguishes persons or things that are grouped together from those that are left out of the group and that differentia must have a rational nexus to the object sought to be achieved by the statute in question."
- 43. As regards unreasonable and irrational classification, learned counsel for the writ petitioners invited our attention to the decision in **APM Terminals B.V. v. Union of India (UOI) and Ors.** reported in (2011) 6 SCC 756, wherein the Hon'ble Apex Court held as under:

"66. Normally, the Courts do not interfere with policy decisions of the Government unless they are arbitrary or offend any of the provisions of the Constitution. In the present cases, the adoption of such a course would, in our view, be apposite.

67. It has been the consistent view of this Court that a change in policy by the Government can have an overriding effect over private treaties between the Government and a private party, if the same was in the general public interest and provided such change in policy was guided by reason. Several decisions have been cited by the parties in this regard in the context of preventing private monopolization of port activities to an extent where such private player would assume a dominant position which would enable them to control not only the berthing of ships but the tariff for use of the port facilities.

69. As was held in **Shimnit Utsch India Private Ltd. v. West Bengal Transport Infrastructure Development Corporation Limited and Ors.** [(2010) 6 SCC 303], the Government was entitled to change its policies with changing circumstances and only on grounds of change a policy does not stand vitiated. It was further held that Government has the discretion to adopt a different policy, alter or change its policy to make it more effective. The only qualifying condition is that such change in policy must be free from arbitrariness, irrationality, bias and malice and must be in conformity with the principle of Wednesbury reasonableness."

44. In the matter of unconstitutionality, on the basis of violation of Article 21 of the Constitution of India, learned counsel for the writ petitioners invited our attention to the decision in **Justice K.S. Puttaswamy and Ors. v. Union of India (UOI) and Ors**. reported in (2017) 10 SCC 1, wherein the Hon'ble Apex Court held as under:

"107. In Kesavananda Bharati v. State of Kerala [(1973) 4 SCC 225] ("Kesavananda Bharati"), Chief Justice Sikri noticed that the Preamble is a part of the Constitution. The Preamble emphasises the need to secure to all citizens justice, liberty, equality and fraternity. Together they constitute the founding faith or the blueprint of values embodied with a sense of permanence in the constitutional document. The Preamble speaks of securing liberty of thought, expression, belief, faith and worship. Fraternity is to be promoted to assure the dignity of the individual. The individual lies at the core of constitutional focus and the ideals of justice, liberty, equality and fraternity animate the vision of securing a dignified existence to the individual. The Preamble envisions a social ordering in which fundamental constitutional values are regarded as indispensable to the pursuit of happiness. Such fundamental values have also found reflection in the foundational document of totalitarian regimes in other parts of the world. What distinguishes India is the adoption of a democratic way of life, founded on the Rule of law. Democracy accepts

differences of perception, acknowledges divergences in ways of life, and respects dissent.

#### **Jurisprudence on dignity**

108. Over the last four decades, our constitutional jurisprudence has recognised the inseparable relationship between protection of life and liberty with dignity. Dignity as a constitutional value finds expression in the Preamble. The constitutional vision seeks the realisation of justice (social, economic and political); liberty (of thought, expression, belief, faith and worship); equality (as a guarantee against arbitrary treatment of individuals) and fraternity (which assures a life of dignity to every individual). These constitutional precepts exist in unity to facilitate a humane and compassionate society. The individual is the focal point of the Constitution because it is in the realisation of individual rights that the collective well being of the community is determined. Human dignity is an integral part of the Constitution. Reflections of dignity are found in the guarantee against arbitrariness (Article 14), the lamps of freedom (Article 19) and in the right to life and personal liberty (Article 21).

118. Life is precious in itself. But life is worth living because of the freedoms which enable each individual to live life as it should be lived. The best decisions on how life should be lived are entrusted to the individual. They are continuously shaped by the social milieu in which individuals exist. The duty of the state is to safeguard the ability to take decisions-the autonomy of the individual-

and not to dictate those decisions. 'Life' within the meaning of Article 21 is not confined to the integrity of the physical body. The right comprehends one's being in its fullest sense. That which facilitates the fulfillment of life is as much within the protection of the guarantee of life.

259. The Constitution has evolved over time, as judicial interpretation, led to the recognition of specific interests and entitlements. These have been subsumed within the freedoms and liberties guaranteed by the Constitution. Article 21 has been interpreted by this Court to mean that life does not mean merely a physical existence. It includes all those faculties by which life is enjoyed. The ambit of 'the procedure established by law' has been interpreted to mean that the procedure must be fair, just and reasonable. The coalescence of Articles 14, 19 and 21 has brought into being a jurisprudence which recognises the inter-relationship between rights. That is how the requirements of fairness and non-discrimination animate both the substantive and procedural aspects of Article 21. These constitutional developments have taken place as the words of the Constitution have been interpreted to deal with new exigencies requiring an expansive reading of liberties and freedoms to preserve human rights under the Rule of law. India's brush with a regime of the suspension of life and personal liberty in the not too distant past is a grim reminder of how tenuous liberty can be, if the judiciary is not vigilant. The interpretation of the Constitution frozen cannot be by its original

understanding. The Constitution has evolved and must continuously evolve to meet the aspirations challenges of the present and the future. Nor can judges foresee every challenge and contingency which may arise in the future. This is particularly of relevance in an age where technology reshapes our fundamental understanding of information, knowledge and human relationships that was unknown even in the recent past. Hence as Judges interpreting the Constitution today, the Court must leave open the path for succeeding generations to meet the challenges to privacy that may be unknown today.

260. The impact of the decision in Cooper is to establish a link between the fundamental rights guaranteed by Part III of the Constitution. The immediate consequence of the decision is that a law which restricts the personal liberties contained in Article 19 must meet the test of permissible restrictions contemplated by Clauses 2 to 6 in relation to the fundamental freedom which is infringed. Moreover, since the fundamental rights are inter-related, Article 21 is no longer to be construed as a residue of rights which are not specifically enumerated in Article 19. Both sets of rights overlap and hence a law which affects one of the personal freedoms Under Article 19 would, in addition to the requirement of meeting the permissible restrictions contemplated in clauses 2 to 6, have to meet the parameters of a valid 'procedure established by law' Under Article 21 where it impacts on life or personal liberty. The

law would be assessed not with reference to its object but on the basis of its effect and impact on the fundamental rights. Coupled with the breakdown of the theory that the fundamental rights are water-tight compartments, the post Maneka jurisprudence infused the test of fairness and reasonableness in determining whether the 'procedure established by law' passes muster Under Article 21. At a substantive level, the constitutional values underlying each Article in the Chapter on fundamental rights animate the meaning of the others. This development of the law has followed a natural evolution. The basis of this development after all is that every aspect of the diverse guarantees of fundamental rights deals with human beings. Every element together with others contributes in the composition of the human personality. In the very nature of things, no element can be read in a manner disjunctive from the composite whole. The close relationship between each of the fundamental rights has led to the recognition of constitutional entitlements and interests. Some of them may straddle more than one, and on occasion several, fundamental rights. Yet others may reflect the core value upon which the fundamental rights are founded. Even at the birth of the Constitution, the founding fathers recognised in the Constituent Assembly that, for instance, the freedom of speech and expression would comprehend the freedom of the press. Hence the guarantee of free speech and expression has been interpreted to extend to the freedom of the press.

Recognition of the freedom of the press does not create by judicial fiat, a new fundamental right but is an acknowledgment of that, which lies embedded and without which the guarantee of free speech and expression would not be complete. Similarly, Article 21 has been interpreted to include a spectrum of entitlements such as a right to a clean environment, the right to public health, the right to know, the right to means of communication and the right to education, besides a panoply of rights in the context of criminal law and procedure in matters such as handcuffing and speedy trial. The rights which have been held to flow out of Article 21 include the following:

- (i) The right to go abroad-Satwant Singh Sawhney v. D. Ramarathnam APO New Delhi [(1967) 3 SCR 525].
- (ii) The right against solitary confinement-Sunil Batra v. Delhi Administration [(1978) 4 SCC 494].
- (iii) The right of prisoners against bar fetters-Charles Sobraj v. Supdt. Central Jail [(1978) 4 SCC 104].
- (iv) The right to legal aid-M.H. Hoskot v. State of Maharashtra [(1978) 3 SCC 544].
- (v) The right to speedy trial-Hussainara Khatoon v. Home Secretary, State of Bihar [(1980) 1 SCC 81].
- (vi) The right against handcuffing-Prem Shankar Shukla v. Delhi Administration [(1980) 3 SCC 526].
- (vii) The right against custodial violence-Sheela Barse v. State of Maharashtra [(1983) 2 SCC 96].
- (viii) The right against public hanging-A.G. of India v. Lachma Devi [(1989) Suppl.(1) SCC 264].
- (ix) Right to doctor's assistance at government hospitals-Paramanand Katara v. Union of India [(1989) 4 SCC 286].

- (x) Right to shelter-Shantistar Builders v. N.K. Totame [(1990) 1 SCC 520].
- (xi) Right to a healthy environment-Virender Gaur v. State of Haryana [(1995) 2 SCC 577].
- (xii) Right to compensation for unlawful arrest-Rudal Sah v. State of Bihar [(1983) 4 SCC 141].
- (xiii) Right to freedom from torture-Sunil Batra v. Delhi Administration [(1978) 4 SCC 494].
- (xiv) Right to reputation-Umesh Kumar v. State of Andhra Pradesh [(2013) 10 SCC 591].
- (xv) Right to earn a livelihood-Olga Tellis v. Bombay Municipal Corporation [(1985) 3 SCC 545].

Neither is this an exercise in constitutional amendment brought about by judicial decision nor does it result in the creation of a new set of fundamental rights. The exercise has been one of interpreting existing rights guaranteed by the Constitution and while understanding the core of those rights, to define the ambit of what the right comprehends.

295. Above all, it must be recognized that judicial review is a powerful guarantee against legislative encroachments on life and personal liberty. To cede this right would dilute the importance of the protection granted to life and personal liberty by the Constitution. Hence, while judicial review in constitutional challenges to the validity of legislation is exercised with a conscious regard for the presumption of constitutionality and for the separation of powers between the legislative, executive and judicial institutions, the constitutional power which is vested in the Court must be retained as a vibrant means of protecting the lives and freedoms of individuals.

318. Life and personal liberty are inalienable rights. These are rights which are inseparable from a dignified human existence. The dignity of the individual, equality between human beings and the quest for liberty are the foundational pillars of the Indian Constitution.

319. Life and personal liberty are not creations of the Constitution. These rights are recognised by the Constitution as inhering in each individual as an intrinsic and inseparable part of the human element which dwells within.

325. Like other rights which form part of the fundamental freedoms protected by Part III, including the right to life and personal liberty Under Article 21, privacy is not an absolute right. A law which encroaches upon privacy will have to withstand the touchstone of permissible restrictions on fundamental rights. In the context of Article 21 an invasion of privacy must be justified on the basis of a law which stipulates a procedure which is fair, just and reasonable. The law must also be valid with reference to the encroachment on life and personal liberty Under Article 21. An invasion of life or personal liberty must meet the three-fold requirement of (i) legality, which postulates the existence of law; (ii) need, defined in terms of a legitimate state aim; and (iii) proportionality which ensures a rational nexus between the objects and the means adopted to achieve them."

45. In support of the contention that the restriction imposed by

the Government is arbitrary and that, the authority has not followed the doctrine of proportionality, before imposing such restrictions etc., learned counsel for the petitioners relied on the decision of the Hon'ble Apex Court in **Anuradha Bhasin and Ors. v. Union of India (UOI) and Ors.** reported in (2020) 3 SCC 637, wherein it was held as under:

"78. In view of the aforesaid discussion, we may summarize the requirements of the doctrine of proportionality which must be followed by the authorities before passing any order intending on restricting fundamental rights of individuals. In the first stage itself, the possible goal of such a measure intended at imposing restrictions must be determined. It ought to be noted that such goal must be legitimate. However, before settling on the aforesaid measure, the authorities must assess the existence of any alternative mechanism in furtherance of the aforesaid goal. The appropriateness of such a measure depends on its implication upon the fundamental rights and the necessity of such measure. It is undeniable from the aforesaid holding that only the least restrictive measure can be resorted to by State, taking into consideration the facts and circumstances. Lastly, since the order has serious implications on the fundamental rights of the affected parties, the same should be supported by sufficient material and should be amenable to judicial review.

79. The degree of restriction and the scope of the same, both territorially and temporally, must stand in relation to

what is actually necessary to combat an emergent situation.

80. To consider the immediate impact of restrictions upon the realization of the fundamental rights, the decision maker must prioritize the various factors at stake. Such attribution of relative importance is what constitutes proportionality. It ought to be noted that a decision which curtails fundamental rights without appropriate justification will be classified as disproportionate. The concept of proportionality requires a restriction to be tailored in accordance with the territorial extent of the restriction, the stage of emergency, nature of urgency, duration of such restrictive measure and nature of such restriction. The triangulation of a restriction requires the consideration of appropriateness, necessity and the least restrictive measure before being imposed."

- 46. That apart, learned counsel for the writ petitioners relied on the decisions in CSIR and Ors. v. Ramesh Chandra Agrawal and Ors. [(2009) 3 SCC 35]; Sanchit Bansal and Ors. v. The Joint Admission Board (JAB) and Ors. [AIR 2012 SC 214]; Nature Lovers Movement v. State of Kerala and Ors. [ILR 2000 (3) Kerala 19]; and State of M.P. and Ors. v. Mala Banerjee [(2015) 7 SCC 698].
- 47. In order to have a better understanding of the issues raised, the relevant notifications issued by State and Union Government are extracted hereunder:

48. Circular No.NHM/3821/ADMIN1/2020/SPMSU dated 29.05.2021 issued by the National Health Mission, Thiruvananthapuram (Exhibit-P1) is extracted hereunder:

#### "NATIONAL HEALTH MISSION CIRCULAR

Circular No: Dated, Thiruvananthapuram, 29.05.2021 NHM/3821/ADMIN1/2020/SPMSU

Sub:- Guidelines for issuance of COVID-19 certificate for persons travelling abroad

Ref :- G.O.(Rt) No.1155/2021/H&FWD dated 28.05.2021

As per the GO cited in Ref. 1, State government has given directions regarding COVID vaccination and issuance of COVID vaccination certificate for persons travelling abroad (Annexure I). In this regard following guidelines are issued to assist the districts in the implementation of the Government Order:

#### 1. State Issued COVID vaccination Certificate.

1.1 Those beneficiaries (above 18 years) who are travelling abroad and wants to get the State Issued COVID Vaccination certificate, with Passport number and/or vaccine name added (in case of Covishield) as mentioned in GO must apply for the same through https://covid19. kerala.gov.in/vaccine/. Detailed process for application is given in **Annexure II**. Beneficiaries may apply for Final/Provisional certificate based upon their current vaccination status by uploading the relevant documents supporting the same. Beneficiaries who have taken Covaxin

and wants certificate with passport number added to it can also apply.

1.2 Applications thus submitted will be verified by the concerned District Medical Officer/ Officer designated by DMO and the application will be approved/rejected. Once approved digital certificate will be issued, and Beneficiary will get an SMS confirmation regarding the same. Certificate can then be downloaded from the portal (https://covid19.kerala.gov.in/vaccine/).

#### 2. Verification/ Approval of request for certificate

2.1 District Medical Officer is authorised as the competent authority to issue the certificate. DMOs may identify a dedicated team ably guided by RCHO, to ensure the issuance of certificate in a time bound manner. Detailed process for verification and approval of application is given in **Annexure III**.

## 3. Provision of $2^{nd}$ Dose of Covishield at 4-6 weeks interval

3.1 Those beneficiaries (>18 years), who are partially vaccinated and are yet to complete 84 days after first dose of Covishield, but needs the completion of vaccination schedule for travelling abroad may apply for priority vaccination through the e Health portal with documents supporting immediate travel and can get vaccinated at 4-6 weeks interval after first dose, once the application is approved and subsequently scheduled for vaccination by District RCHO.

- 3.2 As the second dose of Covishield is administered before the prescribed time interval of MOHFW, GOI (12-16 weeks), it will not be possible to document the same in CoWIN portal. Hence, a separate register must be maintained in Covid Vaccination Centres to document such vaccinations and a certificate must be issued by the Medical officer of the concerned CVC in the format given in **Annexure IV**.
- 3.3 Beneficiary may then apply for State issued Final certificate through the portal as mentioned in Point 1.1. 3.4 Covishield procured by State through other than GOI channel may be used for vaccinating such beneficiaries.

### 4. 2<sup>nd</sup> Dose of Covishield for those who have taken first dose from abroad.

- 4.1 In case of beneficiaries who took first dose of Astrazeneca vaccine from abroad and are currently due for second dose (completed 84 days), they may be administered with one dose of Covishield after registering such beneficiaries for Dose 2 in CoWIN through Vaccinator module, documenting the necessary details of first dose.
- 4.2 If such a beneficiary has not completed 84 days, but needs vaccination at 4-6 weeks interval, then he/she must follow the steps described in points 3.1- 3.3.

### 5. First dose of COVID Vaccine for people going abroad

5.1 Beneficiaries who are planning to go abroad and are yet to receive first dose must register in CoWIN using Passport as ID card type so that Passport number gets documented in CoWIN certificate.

- 5.2 While scheduling the beneficiaries who have applied for priority under "going abroad" category, Districts may preferably allot them to Covishield sessions, as of the two vaccines, Covishield and Covaxin, only Covishield is currently approved by WHO and accepted by most of the foreign countries.
- 6. The Additional Director (FW) shall ensure sufficient training to all concerned and monitor implementation of the Government Order on a daily basis.

Dr. Rathan U. Kelkar, IAS State Mission Director"

49. G.O.(Rt.) No.1155/2021/H&FWD dated 28/05/2021 issued by the Health & Family Welfare (F) Department, Government of Kerala (Exhibit-P2) is extracted hereunder:

#### "ORDER

COVID-19 vaccination drive has entered Phase III from 1 st May 2021 wherein all beneficiaries aged 18 years and above has to be vaccinated and as per the Government order read as 1<sup>st</sup> above, Government have decided to give free vaccinations to all citizens in the age group of 18-45 years. Further, as per the Government order 2<sup>nd</sup> read above Government have notified 32 categories as Front Line Workers for prioritization for COVID-19 vaccination in the age group of 18-45 years as the first lot. Further, as per the Government order 3<sup>rd</sup> paper read above, Government have additionally notified 11 categories as Front Line Workers for

prioritization for COVID-19 vaccination in the age group of 18-45 years as the second lot which includes students / others going to foreign countries, for whom vaccine is compulsory.

- 2. Many countries have stipulated that a valid COVID vaccination certificate is mandatory for issuance of travel clearance and only those certificates with Passport number mentioned in it are accepted by the foreign countries during verification. As per the current settings in CoWIN portal, the details of ID proof which was used at the time of registration in CoWIN will be documented in the COVID vaccination certificate. It is seen that most of these beneficiaries have used aadhar / other IDs rather than Passport during the registration in CoWIN and during the verification process at the time of vaccination. Hence passport number is not documented in the COVID vaccination certificate which is issued by MOHFW through CoWIN portal. This has resulted in a peculiar situation wherein many persons are unable to get travel clearance for going abroad.
- 3. In case of Covishield, the certificate is not considered valid as many countries are demanding certificate with brand name as "Oxford Astrazeneca Vaccine". In addition, as per the new schedule prescribed by Government of India, 2<sup>nd</sup> dose is to be taken at 12-16 weeks interval after first dose. This sudden change has derailed the travel plans for many as they had decided their travel based on the old schedule of 4 6 weeks. In all these cases,

travel process will be initiated only on production of vaccination completion certificate. Many beneficiaries are at the risk of losing their job if they don't report to work place within the stipulated time frame. Further, most of the countries have not included Covaxin in the approved COVID vaccine list and hence those who have taken Covaxin are facing hindrance in getting travel clearance.

- 4. All these issues were brought into the notice of Government of India, to make provisions in CoWIN for permission to include passport details in CoWIN. It was also requested to give permission to the State Government to issue vaccination certificate with changes till provisions are made available in CoWIN. Further, it was requested to permit beneficiaries going abroad to take Covishield as per the previous schedule of 4-6 weeks and to make provisions in the CoWIN portal to document such vaccination given at 4-6 weeks. However, no orders/letters are received from Government of India so far.
- 5. In the above circumstances, Government have pleased to issue the following directions:
- Government of Kerala will issue certificate in the prescribed format (annexed to this Government order) wherein passport number will be recorded and vaccination certificate issued to a person who wishes to go get travel clearance and requires such certificates.
- 2. The District Medical Officer is authorised as the competent authority to issue such certificate of vaccination in the prescribed format.
- 3. Since WHO has already cleared Covishield, the same may be given as preference to people travelling abroad.

- 4. A person who has taken Covishield and wishes to get travel clearance will be eligible for 2<sup>nd</sup> dose of Covishield vaccine after 4 to 6 weeks of the previous schedule. Since currently COVID portal does not permit to administer the 2<sup>nd</sup> dose of Covishield within a period of less than 12 weeks, this is to be recorded separately by the districts.
- 5. Covishield vaccine will be provided from the vaccine procured by the State.
- 6. Districts are to verify any of the under-mentioned documents while providing vaccines in such instances to ensure that the vaccines are administered to eligible persons only
  - a. Live visa
  - b. Admission document for students
  - c. Document of Job confirmation / work permit
- 7. Destination countries policy may also be checked whether vaccination is mandated.

(By order of the Governor)

RAJAN NAMDEV KHOBRAGADE PRINCIPAL SECRETARY"

50. Annexure-R4(a) letter issued by the Secretary, Department of Health and Family Welfare, Government of India, New Delhi dated 7.6.2021 is extracted hereunder:

"D.O. No.2072903/2021/IMMUNIZATION 7<sup>th</sup> June, 2021

Dear Colleague,

The Union Ministry of Health & Family Welfare has received several representations for allowing administration of second dose of Covishield for such persons who have

only taken first dose of Covishield and are seeking to undertake international travel for educational purposes or employment opportunities or as part of India's contingent for Tokyo Olympic games, but whose planned travel dates fall prior to completion of the currently mandated minimum interval of 84 days from the date of first dose.

- 2. Therefore, with a view to provide full coverage of vaccination and facilitating international travel for such genuine reasons, the Ministry has issued the SOPs for the same. A copy of the SOPS is enclosed.
- 3. It is requested that the SOPs may be widely publicized and all necessary measures are taken immediately for implementation of the SOPs.

Warm Regards

Yours sincerely

(Rajesh Bhushan)

#### SOPs on

Administration of Second Dose of Covishield Vaccine Prior to Prescribed Time Interval (after 28 days but before 84 days) to persons intending to undertake international travel for education purpose, for joining employment in foreign countries and for India's contingent to Tokyo Olympics.

- 1. Presently, based on the recommendations by National Expert Group on Vaccine Administration for COVID-19 (NEGVAC). the schedule of Covishield vaccine under National Covid-19 Vaccination Strategy is to administer the  $2^{\rm nd}$  dose at 12-16 weeks interval (i.e. after 84 days). after administration of  $1^{\rm st}$  dose.
- 2. The Union Ministry of Health & Family Welfare has received several representations for allowing administration of second dose of Covishield for such persons who have

only taken first dose of Covishield and are seeking to undertake international travel for educational purposes or employment opportunities or for part of India's contingent for Tokyo Olympic games, but whose planned travel dates fall prior to completion of the currently mandated minimum interval of 84 days from the date of first dose.

- 3. The matter has been discussed in Empowered Group 5 (EG-5) and appropriate recommendations have been received. In this context, with a view to provide full coverage of vaccination and facilitating international travel for such genuine reasons, following procedure shall be followed for administration of second dose of Covishield vaccine for such beneficiaries —
- a. This special dispensation will be available to
  - (i) Students who have to undertake foreign travel for the purposes of education.
  - (ii) Persons who have to take up jobs in foreign countries.
  - (iii) Athletes, Sportspersons and accompanying staff of the Indian contingent attending the International Olympic Games to be held in Tokyo.
- b. States/UT governments shall designate a competent authority in each District for according permission for such administration of second dose of Covishield.
- c. The competent authority shall check the following before according a permission for administration of second dose before the period of 84 days after the date of first dose —
- (i) Whether a period of 28 days has elapsed after the date of first dose.
- (ii) Genuineness of the purpose of travel based on documents related to —
- 1. Admission offers or associated formal communications for the purpose of education.

- 2. Whether a person is already studying in a foreign educational institution and has to return to that institution for continuing his/her education.
- 3. Interview calls for a job or offer letters for taking up employment
- 4. Nomination to participate in the Tokyo Olympic games.
- d. It is advised that vaccination may be availed in such cases through Passport which is one of the permissible ID documents as per the current guidelines, so that the passport number is printed in the vaccination certificate. However, if a Passport was not used at the time of administration of first dose, the details of the photo ID Card used for vaccination will be printed in the vaccination certificate and mention of the Passport in the vaccination certificate is not to be insisted upon. Wherever necessary, the competent authority may issue another certificate linking the vaccination certificate with the passport number of the beneficiary.
- e. This facility shall be available to those who need to undertake international travel for these specified purposes in the period up to 31<sup>st</sup> August, 2021.
- f. All technical protocols as prescribed in the Guidelines of the Ministry regarding COVID Vaccination Centres and AEFI management etc. shall have to be followed.
- 4. It is clarified that Covishield, produced by the Serum Institute of India and approved by the DCGI, is one of the vaccines recognised by the WHO for emergency use as on 3<sup>rd</sup> June 2021. The relevant entry is at S.No. 4 of the WHO EUL, available at https://extranet.who.int/pqweb/sites/default/files/documents/Status%20of%20COVID-19%20 Vaccine%20within%20WHO%20EUL-PQ%20evaluation% 20process%20-%203%20June%202021.pdf. Mention of vaccine type as "Covishield" is sufficient and no other qualifying entries are required in the vaccination certificates.
- 5. The Co-WIN system will soon provide the facility for administration of 2<sup>nd</sup> dose in such exceptional cases."

-:64:-

- 51. The documents/Government orders relied on by the learned counsel for the writ petitioners/respondents 1 & 2 herein, in support of his contentions, are reproduced.
- 52. Firstly, Order No. DO No.T-22020/14/2020-Imm dated 14.01.2021 issued by the Ministry of Health and Family Welfare, Government of India, reads as under:

"DO No. T-22020/14/2020-Imm

Date: 14<sup>th</sup> January, 2021

Dear All,

As you are aware that COVID-19 vaccine is scheduled for roll-out in the country on 16<sup>th</sup> January, 2021 and the States/UTs have already received vaccines for the same.

In this regard, a comparative factsheet for both the vaccines that will be used during the introduction have been prepared which contains information on vaccination platform, physical specifications, dosage, cold chain storage requirements, contraindications and minor AEFLs. A detailed note on contraindications and special precautions has also been prepared and is enclosed.

You are requested to kindly disseminate the above mentioned documents to Programme Managers across all levels and through them to cold chain handlers and vaccinators for ready reference.

Yours sincerely,

(Dr. Manohar Agnani)

## <u>Precautions and Contraindications for COVID-19</u> <u>Vaccination</u>

XXXXXXXXXXXXXXXXXXXX

<b>Comparative Sheet for different Covid-19 vaccines, under</b>	<u>er</u>
Indian Government supply	

Indicator	COVISHIELD	COVAXIN
Type of Vaccine	Recombinant COVID-	Whole-Virion
	19 vaccine based on	inactivated
	Viral Vector	Corona Virus
	Technology	Vaccine
No. of doses in	10	20
each vial		
Shelf life	6 months	6 months
Expiry date	Yes	Yes
available on vial		
Vaccine Vial Monitor	Not Available	Not Available
(VVM)		
Route	Intramuscular (IM)	Intramuscular
	Injectable	(IM) Injectable
Physical	Clear to slightly	Whitish
Appearance of	opaque, colourless to	translucent
Vaccine	slightly brown	
Dose	0.5 ml each dose	0.5 ml each dose
Course	2-doses	2-doses
Schedule	4-weeks apart	4-weeks apart
XXXXXXX		

53. Order No.19/31/F2/2020 Health dated 28.04.2021 giving prioritization to the people who are eligible for 2<sup>nd</sup> dose vaccination for COVID-19 reads as under:

## "COVID 19 VACCINATION - 2<sup>nd</sup> Dose eligible people prioritization

#### No.19/13/F2/2020 HEALTH-28th April, 2021

State has been successfully conducting the COVID vaccination drive from 16<sup>th</sup> January onwards. In view of the surge in COVID, as a part of crowd management at the vaccination centre it was instructed to conduct vaccination with prior online booking only from 22<sup>nd</sup> April, 2021 onwards and the Districts have successfully implemented the same. However, due to limited stocks made available by the Min. of Health and Family Welfare, Govt. of India, districts have

been able to open only limited slots and most of the slots are getting booked by new beneficiaries for the first dose. As a result, many of the beneficiaries who are due for second dose are not able to get an online appointment and hence, unable to complete the schedule.

In order to streamline the vaccination to age group above 45 yrs elderly people the following guidelines are issued:

- 1. While scheduling a session at a CVC, priority shall be given to those who are due for a second dose. The second dose of Covishield is to be preferably administered between 6-8 weeks and that of Covaxin at 4-6 weeks after first dose.
- 2. List of the beneficiaries due for the second dose at each Centre can be accessed from the CoWIN portal. CVC Managers shall mobilise these beneficiaries due for 2<sup>nd</sup> dose vaccination with support of ASHA workers, LSGD staff etc., and vaccinate them after adding them to the session through spot allotment.
- 3. Due care shall be taken at the vaccination centres to have a separate counter for elderly people and people with disabilities.
- 4. Only those slots which will be remaining after catering to the second dose beneficiaries as per the duelist, must be published online for booking.
- Eg: If 80 beneficiaries are due for second dose at a particular centre and their daily capacity is 100, then the only 20 slots must be made online, Remaining 80 slots must be utilised for giving second dose through spot allotment.
- 5. In order to avoid crowding at the centre due to spot allotment, while mobilising the eligible beneficiary as said in point 2, each such beneficiary must be given a specific date and time slot for vaccination.

Utmost care shall be taken to ensure covid appropriate behaviour at the Vaccination Centres.

It is hereby also brought to the notice of districts that, as communicated from MOHFW (DO letter number

1920764/64/2020-Imm dated 23<sup>rd</sup> April, 2021), with the implementation of Liberalised Pricing and Accelerated National Covid-19 Vaccination Strategy from 1<sup>st</sup> May, 2021 onwards, Private CVCs will have to procure COVID vaccine directly from manufacturers and will not be getting vaccine from the Ministry supply. Hence, districts are advised to encourage the Private CVC to utilise the balance stock available with them by 30<sup>th</sup> April, 2021. If any stock is left behind after the above said date, it must be made sure that vaccine is administered only to populations above 45 at the nominal rate of Rs.250 which was fixed by the Ministry. Details regarding reimbursement of payments made, (in case of pending vaccine delivery) will be shared once MOHFW/NHA issues guidance in this regard.

Principal Secretary"

54. Order No. NHM/3821/ADMINI/2020/SPMSU dated 16.05.2021 issued by the NHM State Mission Director, providing guidelines for vaccination to 18-44 age group, reads as under:

No. NHM/3821/ADMIN1/2020/SPMSU Dated: 16.05.2021

To

The District Collectors, All Districts District Medical Officers, All Districts

Sir / Madam

Sub:- Vaccination for 18-44 age group - Guidelines issued reg.

Ref:- ------

Citizens belonging to 18-44 years age group have become eligible for COVID vaccine from  $1^{\rm st}$  May, 2021 onwards. As the State procured vaccines are now

available, vaccination for the 18-44 years group will start from 17<sup>th</sup> May, 2021 onwards. In this regard, the following guidelines are being issued regarding the planning and conduct of COVID vaccination sessions.

#### I. Prioritization in 18-44-year groups

- 1. As the vaccine supply is limited when compared to the demand, it has been decided to give priority to the beneficiaries with Comorbidities as listed in **Annexure 1(A)**.
- 2. All such beneficiaries, who are having comorbidities, need to register in https://covid19.kerala.gov.in/vaccine/and upload comorbidity certificate (**Annexure I B**) for getting priority for vaccination. Detailed Steps for registration are given in **Annexure II**
- 3. Only those beneficiaries who gets approval and session scheduling SMS from the Health department must report to the vaccination centres. At the centre, such beneficiaries must produce the appointment SMS, valid photo ID proof and Comorbidity certificate.

## II. Approval and Scheduling of vaccination for eligible beneficiaries.

4. District RCHO/person designated by RCHO will scrutinize each application received in the portal and approve the eligible beneficiaries for priority vaccination. Subsequently, vaccination centre and date for vaccination may be scheduled by the district team based on the availability of the vaccine. Detailed Steps for approval and scheduling are given in **Annexure III**.

#### III. Conduct of session.

5. In CoWIN, in a session created for 45+, vaccination of citizens 45 years, Health Care Workers and Frontline workers as listed by GOI, can be marked. Similarly in case of sessions created for 18+, vaccination of citizens aged 18-44 years and FLW as decided by State government can be vaccinated.

- 6. In cases where vaccination is conducted for the two groups (18+ & 45+) at the same CVC at the same time, it is preferable to have two separate lines and separate verification counters. Two separate sessions must be created in CoWIN also for the two groups. Net Utilisation/ Issue of vaccines for each category must be shown separately in eVIN based on the number of beneficiaries vaccinated in each group.
- 7. All vaccination must be properly documented in CoWIN. For 18-44 years priority groups in addition to this, vaccination needs to be marked in the **ehealth** portal as well.
- 8. It must be ensured that all sessions are conducted following the COVID protocol.

#### IV. Maintenance of stock in eVIN and Stock register

9. As instructed by MOHFW, stock of GOI supply vaccine and State procured vaccine must be maintained separately in eVIN and Stock register. Provisions have been made in eVIN to differentiate the two channels of supply.

#### V. Vaccination of 45 years.

10. First dose vaccination for  $\geq$  45 years will be based on online booking only. Spot registration should not be entertained.

#### VI. Second dose scheduling

- 11. As per the latest guidelines from MOHFW (**Annexure IV**), the second dose of Covishield needs to be taken at an interval of 12-16 weeks after dose and in case of Covaxin the second dose must be taken after 4-6 weeks interval. Hence forth, online as well as on spot registration for second dose will be possible only after 84 days in case of Covishield and 28 days after Covaxin.
- 12. As the feature for reserving online slots for second dose beneficiaries is now available in the CoWIN portal, all the second dose scheduling must be through online booking only. Recent updates made in the CoWIN portal, attached as **Annexure V**.

#### Dr. Rathan U. Kelkar IAS

State Mission Director"

55. D.O.No.1940407/2020/Imm dated 13.05.2021, issued by the Secretary, Department of Health & Family Welfare, Government of India, is extracted hereunder:

D.O. No.1940407/2020/Imm 13<sup>th</sup> May, 2021

Dear Colleague,

"COVID-19 vaccination drive in India has completed 117 days during which we have been able to vaccinate 17.7 crore beneficiaries of which 3.9 crore beneficiaries have completed the two doses schedule of vaccination as per the recommended interval of 4 weeks for Covaxin and 6-8 weeks for Covishield. This has been possible due to the proactive involvement of all States and UTs.

- 2. In view of the emerging scientific evidences, the interval between two doses of a specified COVID-19 vaccine i.e. COVISHIELD, has been revisited by Covid Working Group of The National Technical Advisory Group on Immunization (NTAGI) and subsequently by National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) in its meeting held on 12<sup>th</sup> May 2021. NEGVAC has recommended revision in schedule of Covishield to administer the 2<sup>nd</sup> dose at 12-16 weeks interval after 1<sup>st</sup> dose instead of earlier interval of 6-8 weeks.
- 3. MoHFW, Government of India has since accepted the recommendation of NTAGI and NEGVAC. Therefore, the States and UTs are advised to ensure 2<sup>nd</sup> dose of Covishield to beneficiaries within this stipulated time interval of 12-16 weeks after 1<sup>st</sup> dose.
- 4. I request you to kindly instruct the concerned officials to undertake necessary steps to widely disseminate the message of revised dosing interval amongst programme managers, vaccinators and recipients of COVISHIELD vaccine and ensure adherence of revised dosing interval.

Requisite changes are being carried out in the Co-WIN platform and would be separately communicated to the States/UTs. You are also requested to note that this decision of revised time interval between two doses is applicable only to Covishield and not to Covaxin vaccine.

Warm Regards,

Yours sincerely (Rajesh Bhushan)

#### **Annexure V**

COWIN updates - 15<sup>th</sup> May 2021

- 6. Validations have been put in place to ensure that people from 45+ are not added to sessions for 18-44 and vice versa.
- 7. COVISHIELD **minimum period between the first and second dose has been set to 84 days**. Validations have been put in place to allow appointments (both online and on-spot) only after the requisite minimum period is over. Those who already have an online appointment for 2<sup>nd</sup> dose of COVISHIELD, may also be advised to book later. However, if they so choose, the CoWIN system will permit their vaccination.

56. G.O.(Rt.) No.1102/2021/H&FWD dated 19.05.2021, issued by the Health and Family Welfare Department, Government of Kerala, is extracted hereunder:

# "GOVERNMENT OF KERALA <u>Abstract</u>

Health & Family Welfare Department - Prioritization for Vaccination for Front Line Workers in the age group of 18-45 years - Sanction accorded - Orders issued.

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#### **HEATH & FAMILY WELFARE (F) DEPARTMENT**

G.O.(Rt) No.1102/2021/H&FWD

Dated, Thiruvananthapuram, 19/05/2021

Read: 1. G.O.(Ms) No.85/2021/H&FWD dated 29.04.2021.

- 2. D.O No.1962432/2020/Imm dated 15.05.2021 from Secretary, GoI, Department of Health & Family Welfare, Ministry of Health & Family Welfare.
- 3. Minutes of the Review Meeting Chaired by the Hon'ble Chief Minister on 07.05.2021.

#### **ORDER**

COVID-19 Vaccination drive has entered Phase-3 from  $1^{\rm st}$  May, 2021 wherein all beneficiaries aged 18 years and above has to be vaccinated and as per the Government Order read as  $1^{\rm st}$  paper above State Government decided to give free vaccinations to all citizens in the age group of 18-45 years.

- 2. As per the letter read as 2<sup>nd</sup> paper above, Government of India informed that the State may appropriately decide other categories over and above decided by GOI. As decided in the Expert Committee meeting for prioritization for Vaccination in the age group of 18-45 years, a State level meeting with all the officers was conducted on 17<sup>th</sup> May, 2021.
- 3. Based on the suggestions of the State level meeting and vaccination requests received in the

Department, the Government are pleased to notify the following categories as Front Line Workers for prioritization for vaccination in the age group of 18-45 years as a first lot.

- 1. All workers in Oxygen manufacturing plants, Oxygen Distribution centres, Oxygen filling centres, Drivers of Oxygen tankers
- 2. People with disabilities
- 3. Field staff of Indian Railways
- 4. Railway TTE and Drivers
- 5. Airport Field & Ground Staff
- 6. KSRTC Drivers & Conductors
- 7. Field Journalists of Media
- 8. Vendors at Fish Markets
- 9. Vendors at Vegetable Markets
- 10. Horticorp field staff
- 11. Matsyafed field staff
- 12. Consumer-fed field staff
- 13. KSEB field staff
- 14. Kerala Water Authority field staff
- 15. Petrol Pump Workers
- 16. Ward Health Members
- 17. Sannadhasena Volunteers
- 18. Home delivery agents
- 19. Head load workers
- 20. News Paper distributors
- 21. Milk Distributors
- 22. Staff at Check post
- 23. Staff at Toll Booth
- 24. Hotels and Restaurants Staff
- 25. Staff of Shops providing essential supplies
- 26. Citizen service centres' staff
- 27. Ration shop staff

- 28. Geriatric care workers
- 29. Palliative care workers
- 30. Beverages Corporation workers
- 31. Field officers of Labour Dept.
- 32. Field officers of Telecom Dept.
- 4. The detailed guidelines regarding the registration, vaccination and session planning shall be issued by SMD, NHM and accordingly vaccination to the above mentioned categories shall start immediately.

(By order of the Governor)
RAJAN NAMDEV KHOBRAGADE
PRINCIPAL SECRETARY"

57. G.O.(Rt.) No.1114/2021/H&FWD dated 24.05.2021, issued by the Health and Family Welfare Department, Government of Kerala, is extracted hereunder:

### "GOVERNMENT OF KERALA

#### **Abstract**

Health & Family Welfare Department - Prioritization for Vaccination in the age group of 18-45 years - Modified -Orders issued.

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# **HEALTH & FAMILY WELFARE (F) DEPARTMENT**

G.O.(Rt) No.1114/2021/H&FWD

Dated, Thiruvananthapuram, 24/05/2021

Read: G.O.(Rt) No.1102/2021/H&FWD Dated. 19/5/2021

### **ORDER**

As per Government Order read above, the Government have notified 32 (Thirty Two) categories as

Front Line Workers for prioritization for Covid -19 vaccination in the age group of 18-45 years as a first lot.

- 2. Since the Government have received many requests from various Departments and also from the General Public for vaccination priority, the matter for including more categories in priority groups was discussed in the State Level Committee Meeting. Based on the suggestions of the State Level Committee, the Government are pleased to notify the following categories too in the priority group for Covid -19 vaccination in the age group of 18-45 years.
- 1. Field Staff of Food & Civil Supplies Department
- 2. Field Staff of FCI
- 3. Field Staff of Postal Department
- 4. Field Staff of Social Justice Department
- 5. Field Staff of Women & Child Welfare Department
- 6. Field Staff of Animal Husbandry Department
- 7. Field Staff of Fisheries Department
- 8. Teachers posted in valuation camp of SSLC/HSCNHSC Exams
- 9. Port Staff
- 10. Students /others going to foreign countries, for whom vaccination is compulsory
- 11. Seafarers
- 3. The Government Order read above stands modified to this extent.

(By order of the Governor)

# RAJAN NAMDEV KHOBRAGADE PRINCIPAL SECRETARY"

58. As discussed above, the paramount contention advanced by the learned Assistant Solicitor General for the appellant is that the notifications/orders/SOPs were issued by the appellant, in accordance

with the expert advice given by the National Technical Advisory Group on Immunization and National Expert Group on Vaccine Administration for COVID-19. The said expert agencies were rendering assistance to the Union Government at different stages and even though initially, the experts were of the opinion that the 2<sup>nd</sup> dose of COVISHIELD vaccine can be administered after four weeks and before six weeks, later the experts felt that it would be better to have the second dose of vaccine administered after 45 days, and later, on a deep seated analysis, it was found that it would be better to administer the vaccine after 84 days, i.e., in between 12 to 16 weeks.

- 59. It is true that Annexure-I minutes of the meeting of National Technical Advisory Group on Immunization (NTAGI) dated 13.05.2021 was not brought to the notice of the writ court, at the time of hearing the writ petition. In fact, along with the writ petition, respondents 1 and 2 have produced only the order dated 28.05.2021 and circular issued by the State Government dated 29.05.2021 as regards the early administration of vaccination for the citizens travelling abroad. Initially, Union of India was not made a party in the writ petition and it was only later, the Union of India was impleaded as additional 4<sup>th</sup> respondent.
  - 60. It is significant to note that along with the statement filed

before the writ court, appellant has produced the SOP on administration of second dose of COVISHIELD vaccine prior to the prescribed time interval to persons intending to undertake international travel for education purpose, for joining employment in foreign countries, and for India's contingent to Tokyo Olympics. The said SOP makes it clear that based on the recommendations of the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC), the schedule of COVISHIELD vaccine under National COVID-19 Vaccination Strategy is to administer the second dose at 12-16 weeks' interval (i.e. after 84 days), after administration of 1st dose.

- 61. The said SOP further makes it clear that the Union Ministry of Health & Family Welfare has received several representations for allowing administration of the 2<sup>nd</sup> dose of COVISHIELD vaccine for such persons, who have only taken first dose of COVISHIELD and are seeking to undertake international travel for educational purposes, employment opportunities, etc., and whose planned travel dates fall prior to the completion of currently mandated minimum interval of 84 days from the date of first dose.
- 62. The SOP further makes it clear that the special dispensation would be available only to, (i) students who have to undertake foreign

travel for the purposes of education; (ii) persons who have to take up jobs in foreign countries; and (iii) Athletes, sports persons and accompanying staff of Indian contingent attending international Olympic games to be held in Tokyo.

63. It was also made clear therein that State/UT Governments shall designate a competent authority in each district for according permission for such administration of second dose of COVISHIELD and the competent authority shall check the following before according permission for administration of second dose before the period of 84 days, after the date of first dose, (i) whether a period of 28 days have elapsed, after the date of first dose; (ii) genuineness of the purpose of travel based on documents related to, - (a) admission offers or associated formal communications for the purpose of education, (b) whether a person is already studying in a foreign educational institution and has to return to that institution for continuing his/her education, (c) interview calls for a job or offer letters for taking up employment, and (d) nomination to participate in the Tokyo Olympic games. Apart from the above, other vital aspects are also dealt with in the said SOP, in order to ensure administration of vaccines on an early basis for the classified set of citizens.

- 64. On the basis of the said relaxation provided, it was directed that the CoWIN Portal will soon provide facilities for administration of second dose of such exceptional cases. Therefore, on a conjoint reading of the orders passed by the State Government, SOP issued by the Government of India, and the minutes of the meeting of National Technical Advisory Group on Immunization and National Expert Group on Vaccine Administration for COVID-19 on 13.05.2021, it is clear that the Government of India have taken a decision in the matter of administration of vaccine to a particular class of citizens, in order to ensure that their requirement to go abroad and pursue the intended activities are not affected, if they are bound to travel before 84 days of the administration of first dose of COVISHIELD vaccine.
- 65. As we have discussed above, the contention advanced by learned counsel for the writ petitioners is that there is no reasonableness in the classification made, since even the citizens of such age group are unreasonably classified from administration of the vaccine with a lesser interval, especially due to the fact that the citizens are given the liberty to decide as to whether to take the vaccine or not, and further that the vaccine is permitted to be purchased by the Union Government from the manufacturer, on payment basis. Therefore, according to the learned

counsel, it is not only an arbitrary exercise of power, it is an inference with the personal choice entitled to be expressed by the citizens under Article 21 of the Constitution of India, and the said classification made is not only unreasonable and arbitrary, but also clearly discriminatory, unfair, and interfering with the privacy of the citizens. We are of the considered opinion that the test of reasonableness, discrimination, arbitrariness and classification are to be considered and adjudicated in the anvil of the present scenario of the COVID-19 pandemic, taking into account the provisions of the Disaster Management Act, 2005.

66. The Disaster Management Act, 2005 was brought into force by the Parliament, to provide for the effective management of disasters and for matters connected therewith or incidental thereto, and the Government have decided to enact a law on disaster management to provide for requisite institutional mechanism for drawing up and monitoring the implementation of the disaster management plants, ensuring measures by various wings of Government for prevention and mitigating effects of disasters, and for undertaking a holistic, coordinated and prompt response to any disaster situation. The enactment is also intended to facilitate effective steps for the mitigation of disasters, prepare for, and coordinate effective response to disasters, as also

matters connected therewith or incidental thereto.

- 67. Disaster is defined under Section 2(d) of the Act, 2005, to mean a catastrophe, mishap, calamity or grave occurrence in any area, arising from natural or man made causes, or by accident or negligence which results in substantial loss of life or human suffering or damage to, and destruction of, property, or damage to, or degradation of, environment, and is of such a nature or magnitude as to be beyond the coping capacity of the community of the affected area.
- 68. Disaster management is defined under Section 2(e) to mean a continuous and integrated process of planning, organising, coordinating and implementing measures which are necessary or expedient for—
  - (i) prevention of danger or threat of any disaster;
  - (ii) mitigation or reduction of risk of any disaster or its severity or consequences;
  - (iii) capacity-building;
  - (iv) preparedness to deal with any disaster;
  - (v) prompt response to any threatening disaster situation or disaster;
  - (vi) assessing the severity or magnitude of effects of any disaster."
- 69. Under the Disaster Management Act, 2005, a National Authority and State Authorities are constituted, in order to control and regulate the activities whenever a proclamation is made by the Government in regard to a particular disaster at the International,

National, State, as well as at the level of local administration. Various committees and organisational set up are also envisaged under the Act, and plans are prepared at the National, State, District, and local body levels, to tackle the adverse effects and to contain the disaster in the larger public interest. No doubt, the Union Government, as well as State Governments, are vested with powers to issue necessary orders, instructions, and standard operating procedures, so as to regulate, control, and effectively manage and administer the activities pursuant to any disaster declared by the respective Government.

70. Here is a case where, COVID-19 pandemic is declared by the World Health Organisation and nations at large, as an international pandemic, and different countries are making efforts to control, regulate and to immunize the people of the country, in order to achieve the target and results, at the international level itself, and that is the reason why, even travel restrictions are made inter-State initially and internationally. Even now, there is a ban for international travel, which is being relaxed by the Central Government stage by stage. Therefore, the test of reasonableness and other aspects pointed out by the learned counsel for the writ petitioners have to be considered by this Court, taking into account the powers vested with the Union and State Governments to

regulate and control the emergent situation, resorting to the provisions of the Disaster Management Act, 2005.

- 71. It is an undisputed fact that COVID-19 pandemic is not an ordinary or normal situation prevailing in the country and the attempt of the Union and State Governments are to protect the rights and liberties of the citizens as a group, instead of the situation being managed, taking into account the interest of the individual or a particular group. That is why, the Disaster Management Act, 2005 empowers the Union, as well as the State Governments, to prepare plans at the National, State, District, and local body levels, in order to take appropriate and adequate measures, to contain the spread of COVID-19 pandemic. Moreover, we are made to understand that, like the Kerala State promulgating the Kerala Epidemic Diseases Act, 2021, other States have also taken similar steps, with the hopeful intention of taking such measures, as are contemplated thereunder, for the well being and protection of the citizens at large, and to contain the disease, within the State.
- 72. It may be true that under normal and ordinary circumstances, and especially when, there is no compulsion for taking the vaccine, an individual or group of citizens may have the right to contend that they have personal liberty to decide the period during which vaccines are to

be administered, but in the case on hand, the issue is regulated and controlled by the provisions of Disaster Management Act, 2005, and other special enactments. Insofar as the State of Kerala is concerned, the State Government is issuing notifications/orders/SOPs, also on the basis of the advisories/instructions/orders/notifications/SOPS issued by the Union Government. It is evident from the circulars and notifications produced by the writ petitioners before the writ court dated 29.05.2021 and 28.05.2021 that, they are issued on the basis of the stand adopted by Union of India in regard to administration of vaccine to classified groups to achieve an objective.

73. However, Union Government have felt at one point of time that unless and until early vaccine is administered after the first dose of vaccine, to such group of persons, who are travelling abroad for the purpose of education/treatment/employment/sports activities, serious prejudice would be caused to such persons, which would, in turn, affect the interest of the nation also. It was accordingly, the Union Government have decided to group such persons and classify accordingly for early administration of the second dose of vaccine. In our view, the said approach of the Union Government, cannot be said to be an unreasonable classification, because it was not the intention of the

Government to give prioritization of vaccine before 84 days, but its intention is to ensure that if such persons have to travel abroad before 84 days, they are to be administered with the second dose of vaccine, most importantly for the reason that other countries permitted the citizens of other countries to travel abroad, only if both doses of the vaccine are administered.

74. True that there is no guarantee that persons, who have taken two doses of COVID-19 vaccine, would not get infected with Coronavirus. It is on the basis of scientific study, the authorities concerned have stipulated the time duration for taking the 2<sup>nd</sup> dose of the vaccine. The study is made by evaluating the situations generally, though there could be an exception. Lakhs and lakhs of people are administered with double dose vaccinations in Kerala, but more than 8000 people are still infected. At this juncture, learned counsel for the writ petitioners pointed out one of the contention raised by the writ petitioners before the writ court that Kerala is the State which has reached 92% of first dose. In spite of having 92% of first dose, Kerala is the State which has the most number of COVID-19 cases. Therefore, we cannot say, the medicine is ineffective. Here, the learned counsel submitted that the situation demands an early second dose.

75. There is no specific admission from the Government that within 28 days citizens are permitted to administer vaccination. Government have not said specifically that after 28 days, people can take vaccination. What they have said is, in respect of those cases, when they examined as to whether, partial vaccination is better or double vaccination is better, within this particular intervals, it was observed that because of certain reasons it is a reasonable classification, whatever that be we can consider, because of those reasons, it is better to have to instead of one, which is partial, within the intervals and it is being extended to everybody.

76. Though the learned counsel for the writ petitioners has contended that the vaccine protocol allows the citizens to take the second dose of vaccine after 28 days, because, every vaccine has got a protocol, we do not have any material regarding the vaccine protocol that it can be administered immediately after 28 days. But, when the notification/ orders are read together, the dose interval between the COVISHIELD vaccine has undergone a series of revision based on the available and emergent scientific evidence mentioned therein with overall guidance. Precisely, based on the recommendation, the schedule of COVISHIELD vaccine under the said programme is to administer the

second dose at 12-16 weeks' interval i.e., 84 days after the administering of first dose. This is based on the typical opinion that the duration of 84 days in administering the second dose of COVISHIELD vaccine is providing the best protection to everybody. It does not indicate whether there is a vaccination policy of the company or manufacturer that immediately after 28 days, a second dose has also to be administered.

77. In this context, learned counsel for the writ petitioners submitted that the vaccine or medicine protocol does not indicate as to whether, it should be taken after 28 days, and even for the exempted group, it cannot be taken. To put it differently, if a specified group, who are travelling abroad for educational purposes, Olympics, employment abroad, the efficacy is also tested. In effect, they are also persons for evaluation. We cannot accept the said submission, because it is a policy decision and the evaluation process of the scientists, doctors, and all the experts in the field are going on.

78. The abovesaid view is admitted by the learned counsel for the writ petitioners. In this context, learned counsel for the writ petitioners submitted that from the data what the scientists have gathered is, if the second dose of vaccine is administered after 28 days, the citizens would get only lesser protection. If it is administered after 84 days, the citizens

will get better protection. That is the only study report. Hence, the overall study shows that vaccines can be taken after 28 days. But, after 28 days, one will get only lesser protection and after 84 days one would get better protection. Hence, the Government has insisted that second dose of vaccine should be taken after 84 days. That is the reason for imposing restrictions. That is the question which the learned Single Judge has mooted. An individual has got a right to decide as to whether he/she should be protected at all. When the individual has got such a right, whether he should be protected or not, according to the learned counsel for the writ petitioners, he has also a right to decide to what percentage he should be protected.

79. It is also significant to note that such countries only insisted for the administration of two doses of vaccine and they were not concerned with the efficacy of the second dose of vaccine, taken after 84 days. There also, the Government have taken such a policy decision, taking into account the larger interest of the nation and to protect the international convention treaties and obligations. In our view, the choice made by the Government of India, to administer the second dose of vaccine on a particular group, can never be said to be arbitrary or an unfair action, especially for the reason that nobody has a case that the

Union Government was interested only to protect the interest of those alone, so as to bring in the theory of discrimination, arbitrariness or unfairness or unreasonable classification.

- 80. Apart from all the above aspects, it is a settled legal position in terms of the judgments discussed above that, what is prohibited is only an unreasonable classification, but the instant classification made by the Government on the basis of its policy to meet the international obligations and conventions, and the national interest to protect the interest of the people who are travelling abroad, for various activities referred to above, cannot be said to be an unreasonable classification made by the Union Government.
- 81. It is equally important to note that whenever a particular situation is declared as emergent, under the provisions of the Disaster Management Act, 2005, then the provisions of the said Act supersedes the provisions of any other enactments, to tide over the situations in the best interest of the nation. No doubt, the Disaster Management Act, 2005 is only a subservient legislation to the fundamental rights guaranteed to the citizens under the Constitution of India. But, what is significant according to us is that, the test of unreasonableness, arbitrariness, unfairness, and reasonable/unreasonable classification are

all to be made, considering the larger interest of the nation and severity on which, it is to be dealt with, as per the provisions of the Disaster Management Act, 2005.

- 82. Even though the writ petitioners have raised a contention that they have the right of liberty to make a choice between early protection and better protection, there is no scope for any such individual preference against the interest of the nation and citizens at large. That is why, the Parliament, in the Act, 2005, has made a clear definition to the disaster management to mean, a continuous and integrated process, planning, organising, coordinating and implementing measures, which are necessary and expedient for the national interest. Therefore, in our considered view, the contentions put forth by the writ petitioners in the writ petition, were mostly concerning the protection of the interest of their employees alone, which, if permitted, would definitely interfere with the continuous and integrated activities made by the Union and State Governments.
- 83. Having realised the situation accordingly, we are of the view that Government of India have acted in terms of the scientific and expert advice, based on the studies conducted by them, and therefore, it is not for the Constitutional Courts, to analyse the intrinsic aspects of the same,

in order to arrive at a different conclusion, which is also impermissible in law. Once it is established that the Government have acted on the basis of such advice, it is for the Government to decide how to go about it, in order to get rid of the emergent COVID-19 Pandemic situation, which thus means, such expert advice, on the basis of scientific study, cannot possibly be substituted by a judgment of Constitutional Courts, especially when no materials are produced before the Court to show that the expert and scientific advises given to the Government are hasty, bad or ill advised.

- 84. We are also of the view that once the provisions of the Disaster Management Act, 2005 is invoked by the Government, the individual freedom and interest may have given way to the interest of the citizens of the country at large, failing which, the Government would not be in a position to manage, co-ordinate, and implement the measures and activities taken for protecting the rights and liberties of the citizens at large, rather than self-centric and individual protection of the rights.
- 85. Assimilating the facts and legal circumstances discussed above, we are undoubtedly of the opinion that the classification made by the Central Government to administer the second dose of vaccine before 84

days, classifying a set of people travelling abroad, can never be said to be an unreasonable classification. The edifice of the case built up by the writ petitioners is on the basis of such a classification made by the Union Government and consequential circulars/notifications/orders issued by the State Government. Once we have found that the classification made is reasonable and there is no arbitrariness or unfairness, in the matter of administering second dose of COVISHIELD vaccine, to such persons, on stringent conditions contained in the SOP discussed above, we do not think the writ petitioners have made out a case to grant the relief of securing vaccine and administering the same on the employees of the companies before 84 days.

86. It is equally important to note that even though the vaccine can be purchased by the organisations through hospitals, and administer the same, the control and regulation of the vaccine is still with the CoWIN Portal managed by the Government of India, which itself is a clear indicator that no citizen can be permitted to activate the process of administering the vaccine on individual interest. This we say because, the duration of administering first and second doses of vaccine was varied at different times and finally reached now at 84 days, which is on the basis of advice given by the advisory and expert bodies of the Union of India

and for acquiring herd immunity, which can never be seen otherwise than to protect the interest of the nation.

87. In the light of the above, the judgment of the learned Single Judge dated 3.9.2021 in W.P.(C) No.16501 of 2021 requires interference. The direction issued by the learned Single Judge that the authorities shall regulate the CoWIN Portal, so as to enable the scheduling of the second dose of COVISHIELD vaccine after four weeks of the first dose, for those who want to accept the second dose, after a period of four weeks, cannot be sustained under law. Viewed from that angle, if the CoWIN Portal is to be redefined as directed by the learned Single Judge, it can have a national implication, which would derail or upset the activities controlled and regulated by the Central and State Governments and would be quite detrimental to the interest of the nation.

Upshot of the above discussion is that this Writ Appeal is allowed and the impugned judgment is set aside. Consequently, the writ petition is dismissed.

Sd/-S. Manikumar, Chief Justice

Sd/-Shaji P. Chaly, Judge

# **APPENDIX**

# **APPELLANT'S ANNEXURES:**

A1:- MINUTES OF THE MEETING DATED 13.05.2021 OF THE STANDING TECHNICAL SUB COMMITTEE.

# **RESPONDENTS' ANNEXURES:**

ANNEX.-1: A DETAILED LIST SHOWING THE DETAILS & DATES OF VACCINATION OF THE 1ST DOSE AND 2ND DOSE.

ANNEX.-2: A LETTER ISSUED BY THE SABINE HOSPITAL AND RESEARCH CENTRE, MUVATTUPUZHA DATED 28.09.2021.

//TRUE COPY//

P.A. TO C.J.