IN THE HIGH COURT OF JUDICATURE AT BOMBAY

CIVIL APPELLATE JURISDICTION

PUBLIC INTREST LITIGATION NO. 85 OF 2021

Yohan Tengra **.... Petitioner**

Versus

State of Maharashtra & Ors. **.... Respondents**

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STAND OF UNION OF INDIA REGARDING DISCRIMINATION BETWEEN VACCINATED & UNVACCINATED.

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SUMMARY OF CENTRAL GOVERNMENT'S GUIDELINES REGARDING COVID-19 VACCINATION AND AGAINST DISCRIMINATION BETWEEN VACCINATED AND UNVACCINATED AS GIVEN IN DIFFERENT AFFIDAVITS, NATIONAL PLAN AND IN REPLY GIVEN UNDER RTI AND REPLY GIVEN IN LOK SABHA.

1. The Counter Affidavit filed in the matter of **Jacob Puliyel Vs Union of India numbered as Writ Petition (Civil) No. 607 of 2021** by the Central Government on **28.11.2021**, by **Dr. P.B.N. Prasad**, working as Joint Drugs Controller (India), Central Drugs Standard Control Organisation, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India makes it clear that no services or benefits are linked with the vaccination. The relevant **Paragraph 64** reads as under;

> *"64. **In so far as the Petitioner's submissions regarding Covid 19 vaccine being mandatory, as per the Operational Guidelines document, COVID-19 vaccination is voluntary.** However, it is emphasised and encouraged that all individuals take vaccination for public health and in his/ her interest as well as public interest since in case of pandemic, an individual's ill health has a direct effect on the society. **Covid-19 vaccination is also not linked to any benefits or services.** Therefore, any submissions made by the Petitioner to the contrary, in so far as the Answering Respondents are concerned, is denied."*

2. The summary of Covid-19 vaccination guidelines given by the Central Government in a recent affidavit dated 13th January, 2022 submitted before Supreme Court in the case of between **Evara Foundation Vs. Union of India Writ Petition (Civil) No. 580 of 2021** on behalf of Union of India

which is affirmed by Dr. Veena Dhawan, Joint Commissioner (UIP) in the Ministry of Health & Family Welfare, Government of India, it is once again made clear that;

(i) The vaccination is voluntary and no one can be given vaccine against his wish.

(ii) No one should be required to carry & show the vaccination certificate to any authority.

(iii) Before giving vaccines to anyone each person should be informed about adverse side effects of vaccines by the person/doctor giving vaccines.

3. That, in affidavit dated **8.10.2021** by Shri. Satyendra Singh, Under Secretary Health Ministry of India before Hon'ble Bombay high Court in **Writ Petition No. 1820 of 2021**, it is made clear that the COVID-19 vaccination is completely voluntary for all citizens of India and Ministry of Health and Family Welfare, Government of India has not formulated or suggested any policies for discrimination between citizens of India on the basis of their vaccination status. The relevant paras of the affidavit read as under;

> "***9****. That, it is further humbly submitted that the directions and guidelines released by Government of India and Ministry of Health and family Welfare, do not entail compulsory or forcible vaccination against COVID-19 disease implying that* ***COVID-19 vaccination is completely voluntary for all citizens of India. Ministry of Health and Family Welfare, Government of India has not formulated or suggested any***

policies for discrimination between citizens of India on the basis of their vaccination status.

10. *That, it is duly advised, advertised and communicated by MoHFW through various print and social media platforms that all citizens should get vaccinated, but this in no way implies that any person can be forced to be vaccinated against her / his wishes.*

11. *That, as per the existing guidelines, there is no provisions for forcing any citizen to book appointment for Covid Vaccination on Co-WIN or visiting Covid Vaccination Centre for vaccination if a person above the age of 18 years visits a Covid Vaccination Centre by her / his choice for vaccination and asks for the same, it implies that she / he is voluntarily coming to the center to get the benefit of Covid Vaccination."*

4. That in the reply under RTI given by the Health Ministry on **01.03.2021** makes it abundantly clear that the various facilities such as train travels, salary etc. cannot be connected with the vaccination status of a person.

The relevant Question & Answer are reproduced as under;

The Central Government's reply dated **01.03.2021** to an application under RTI is as under;

"RTI reply by Government of India's Health Ministry on 1.03.2021 to Shri. Anurag Sinha

प्रश्न १: कोरोना वैक्सीन लेना स्वैच्छिक है या अनिवार्य , जबरदस्ती?

उत्तर : *कोरोना वैक्सीन लेना स्वैच्छिक है।*

Q1. Is taking corona vaccine, voluntary or mandatory, forced?

Ans. *It is voluntary to take corona vaccine.*

प्रश्न २ : क्या वैक्सीन नहीं लेने पर सारी सरकारी सुविधाए बंद कर दी जायगी, सरकारी योजना पेंशन ?

उत्तर ***:*** *आवेदन में लिखी बातें निराधार है। किसी भी सरकारी सुविधा, नागरिकता, नौकरी इत्यादि से वैक्सीन का कोई सम्बन्ध नहीं है।*

Q2. If you do not take vaccine, will all government facilities, like government pension scheme, be discontinued?

Ans. *The things written in the application are baseless. Vaccine has nothing to do with any government facility, citizenship, job, etc.*

प्रश्न ३ : क्या वैक्सीन नहीं लेने पर नौकरी नहीं मिलेगा, ट्रेन, बस, मेट्रो में चढ़ने नहीं मिलेगी?

उत्तर ***:****आवेदन में लिखी बातें निराधार है। किसी भी सरकारी सुविधा, नागरिकता, नौकरी इत्यादि से वैक्सीन का कोई सम्बन्ध नहीं है।*

Q3. If you do not take vaccine, will you not get a job; not allowed to board train, bus, metro?

Ans. *The things written in the application are baseless. Vaccine has nothing to do with any government facility, citizenship, job, etc.*

प्रश्न ४: यदि कोई IAS, IPS स्वास्थ्य या पुलिस कर्मचारी नागरिक को धमकी दे की वैक्सीन ले नही तो ये कर देगे तो नागरिक क्या कर सकती क्या कोर्ट जा सकते हैं?

उत्तर ***:*** *आवेदन में लिखी बातें निराधार है। किसी भी सरकारी सुविधा, नागरिकता, नौकरी इत्यादि से वैक्सीन का कोई सम्बन्ध नहीं है।*

Q4. If an IAS, IPS, health or police personnel threatens a citizen to take vaccine then what can a citizen do, can he approach the Court?

Ans. *The things written in the application are baseless. Vaccine has nothing to do with any government facility, citizenship, job, etc.*

प्रश्न ५: क्या वैक्सीन नहीं लेने पर स्कूलों, कॉलेज, विश्वविद्यालय, गैस कनेक्शन, पानी, बिजली कनेक्शन, राशन आदि के लिए क्या वैक्सीन नहीं मिलेगे ?

उत्तर : *आवेदन में लिखी बातें निराधार है। किसी भी सरकारी सुविधा, नागरिकता, नौकरी इत्यादि से वैक्सीन का कोई सम्बन्ध नहीं है।*

Q5. If vaccine is not taken then will the facilities such as school, college, university, gas connection, water and electricity connection, ration be made unavailable to them?

Ans. *The things written in the application are baseless. Vaccine has nothing to do with any government facility, citizenship, job, etc.*

प्रश्न ६ : क्या वैक्सीन नही लेने पर नौकरी से निकला जा सकता है वेतन रोका जा सकत है, निजी और सरकारी विभाग दोनों मे?

उत्तर : *आवेदन में लिखी बातें निराधार है। किसी भी सरकारी सुविधा, नागरिकता, नौकरी इत्यादि से वैक्सीन का कोई सम्बन्ध नहीं है।*

Q6. If vaccine is not taken can the person be fired from his job, his salary be withheld, in both, private and government offices?

Ans. *The things written in the application are baseless. Vaccine has nothing to do with any government facility, citizenship, job, etc.*"

5. The Disaster Management Plan forbids all types of discrimination.

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Chapter: 1.7 Social Inclusions

Hazards do not discriminate based on human social conditions, but human responses to disasters often do. Existing socio-economic conditions mean that disasters can lead to different outcomes for demographically similar communities, where the most vulnerable groups also suffer disproportionately on multiple counts compared to others. The preamble of NPDM 2009 notes that the economically weaker and socially marginalized sections, women, Scheduled Castes, Scheduled Tribes and minorities tend to suffer more during disasters. **The DM Act 2005 specifically forbids all forms of discrimination** – be it based on sex, caste, community, descent or religion – in any aspect of DM. **Social inclusion is about equality of rights and opportunities, dignity of the individual, acknowledging diversity, and contributing to resilience for everyone, not leaving aside members of a community based on age, gender, disability or other.**

6. Hon'ble Supreme Court in the case of **Centre for Public Interest Litgation vs. Union Of India 2020 SCC OnLine SC 752,** made it clear that not only the national plan but also the guidelines, directions, orders, SOPs of nodal ministry i.e. Health Ministry are to be followed by the state authorities.

It is ruled as under;

> *"40. The Disaster Management Act, 2005 contain* ***ample powers and measures, which can be taken by the National Disaster Management Authority, National Executive Committee and Central Government to prepare further plans, guidelines and Standard Operating Procedure (SOPs), which in respect to COVID-19 have been done from time to time. Containment Plan for Novel Coronavirus, 2019 has been issued by Ministry of Health and Family Welfare, Government of India, copy of which updated up to 16.05.2020 has been brought on record as Annexure-R4. There are no lack of guidelines, SOPs and Plan to contain COVID-19, by Nodal Ministry and Annexure R-6 has been brought on record*** *issued by Ministry of Health and Family Welfare, Government of India, i.e., Updated Containment Plan for Large Outbreaks Novel Coronavirus Disease, 2019 (COVID-19).*
>
> *41. National Executive Committee as well as Nodal Ministry has issued guidelines and orders from time to time to regulate all measures to contain COVID-19. The petitioners are not right in their submissions that there is no sufficient plan to deal with COVID- 19 pandemic. …."*

7. Hon'ble Supreme Court had also taken the note of this fact and in the case of **Mazdoor Sabha Vs. State of Gujarat (2020) 10 SCC 459** and had observed that the ***challenges of Covid-19 are to be resolved by the State Governments within the domain of their functioning under the law, in coordination with the Central Government***. It is ruled as under;

> ***"30.*** *Even if we were to accept the respondent's argument at its highest, that the pandemic has resulted in an internal disturbance,*

we find that the economic slowdown created by the COVID-19 Pandemic does not qualify as an internal disturbance threatening the security of the State. The pandemic has put a severe burden on existing, particularly public health, infrastructure and has led to a sharp decline in economic activities. ***The Union Government has taken recourse to the provisions of the Disaster Management Act, 2005. [Ministry of Home Affairs, Order No. 40-3/2020-DM-I(A) dated 24-3-2020.]*** *However, it has not affected the security of India, or of a part of its territory in a manner that disturbs the peace and integrity of the country.* ***The economic hardships caused by COVID-19 certainly pose unprecedented challenges to governance. However, such challenges are to be resolved by the State Governments within the domain of their functioning under the law, in coordination with the Central Government…."***

49. *This Court is cognizant that the respondent aimed to ameliorate the financial exigencies that were caused due to the pandemic and the subsequent lockdown. However, financial losses cannot be offset on the weary shoulders of the labouring worker, who provides the backbone of the economy. Section 5 of the Factories Act could not have been invoked to issue a blanket notification that exempted all factories from complying with humane working conditions and adequate compensation for overtime, as a response to a pandemic that did not result in an "internal disturbance" of a nature that posed a "grave emergency" whereby the security of India is threatened. In any event, no factory/classes of factories could have been exempted from compliance with provisions of the Factories Act, unless an "internal disturbance" causes a grave emergency that threatens the security of the State, so*

as to constitute a "public emergency" within the meaning of Section 5 of the Factories Act. We accordingly allow the writ petition and quash Notification No. GHR/2020/56/FAC/142020/346/M3 dated 17-4-2020 and Notification No. GHR/2020/92/FAC/142020/346/M3 dated 20-7-2020 issued by the Labour and Employment Department of the respondent State.

8. In **Noida Entrepreneurs Association Vs. Noida & Others (2011) 6 SCC 508** it is ruled as under;

"25.** It is a settled proposition of law that whatever is prohibited by law to be done, cannot legally be affected by an indirect and circuitous contrivance on the principle of quando aliquid prohibetur, prohibetur at omne per quod devenitur ad illud, which means **"whenever a thing is prohibited, it is prohibited whether done directly or indirectly…

41.** Power vested by the State in a public authority should be viewed as a trust coupled with duty to be exercised in larger public and social interest. Power is to be exercised strictly adhering to the statutory provisions and fact situation of a case. **"Public authorities cannot play fast and loose with the powers vested in them."

A decision taken in an arbitrary manner contradicts the principle of legitimate expectation. An authority is under a legal obligation to exercise the power reasonably and in good faith to effectuate the purpose for which power stood conferred. In this context, "in good faith" means "for legitimate reasons". It must be exercised bona fide for the purpose and for none other."

सत्यमेव जयते

NATIONAL DISASTER MANAGEMENT PLAN

November 2019

NATIONAL DISASTER MANAGEMENT AUTHORITY
MINISTRY OF HOME AFFAIRS
GOVERNMENT OF INDIA

1.7 Social Inclusion

Hazards do not discriminate based on human social conditions, but human responses to disasters often do. Existing socio-economic conditions mean that disasters can lead to different outcomes for demographically similar communities, where the most vulnerable groups also suffer disproportionately on multiple counts compared to others. The preamble of NPDM 2009 notes that the economically weaker and socially marginalized sections, women, Scheduled Castes, Scheduled Tribes and minorities tend to suffer more during disasters. The DM Act 2005 specifically forbids all forms of discrimination – be it based on sex, caste, community, descent or religion – in any aspect of DM. Social inclusion is about equality of rights and opportunities, dignity of the individual, acknowledging diversity, and contributing to resilience for everyone, not leaving aside members of a community based on age, gender, disability or other.

IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

WRIT PETITION (CIVIL) NO. 607 of 2021

IN THE MATTER OF:

DR. JACOB PULIYEL …PETITIONER

VERSUS

UNION OF INDIA & ORS. …RESPONDENTS

COUNTER AFFIDAVIT ON BEHALF OF THE RESPONDENT NO. 1 (MINISTRY OF HEALTH AND FAMILY WELFARE) AND RESPONDENT NO 2. (CENTRAL DRUGS STANDARD CONTROL ORGANISATION)

PAPER-BOOK

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ADVOCATE FOR RESPONDENT 1 & 2: G S MAKKER

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COUNTER AFFIDAVIT ON BEHALF OF THE RESPONDENT NO. 1 (MINISTRY OF HEALTH AND FAMILY WELFARE) AND RESPONDENT NO 2. (CENTRAL DRUGS STANDARD CONTROL ORGANISATION)

I, Dr. P.B.N. Prasad, S/o Sh. P. Somaiah Naidu, aged about 58 years, working as Joint Drugs Controller (India), Central Drugs Standard Control Organisation, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India, do hereby solemnly affirm and state as under, on the basis of information provided to me through official records:

1. That I am working as Joint Drugs Controller (India), Central Drugs Standard Control Organisation, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India. It is submitted that, I am

authorized to represent the Respondents in the above matter and as such I am well conversant with the facts and circumstances of the case on the basis of documents. Hence, I am competent to swear this affidavit.

2. That, I have gone through the contents of the writ petition filed by the Petitioner and I have perused the records pertaining to the case and I am filing this affidavit in reply, on the basis of knowledge derived by me after perusing the records.

3. It is submitted that the Answering Respondents deny and dispute all allegations and contentions raised by the Petitioner in the writ petition. The Answering Respondents humbly submit that the contents of the writ petition are denied, except to the extent admitted below and nothing shall be deemed to have been admitted by the Answering Respondents merely on the ground of non-specific traverse.

4. At the outset, the Respondents seek to raise the following preliminary objections-

(a) It is submitted that this petition is filed purportedly as a Public Interest Litigation. There are very few cases where a purported Public Interest Litigation [whether bonafide or motivated] harms public interest directly. This is

one such petition which, if entertained, would harm public interest.

(b) It is submitted that the year 2020 and 2021 witnessed one of the most severe tragedy engulfing not only India but entire human kind, threatening virtually the existence of the human race. It has posed unprecedented challenges before the human race. Every country started their own earnest efforts to deal with this pandemic called COVID-19. All human efforts throughout the world were concentrated towards tackling this pandemic and also attempting to prevent it.

(c) It was only few countries in the world which succeeded in manufacturing vaccines for protection from Covid-19. India is one of such countries which succeeded in developing its own vaccine and also manufacturing one more vaccine invented in Britain, known respectively as Covaxin and Covishield. As narrated hereunder in detail, there is an elaborate statutory regime which needs to be followed before any vaccination drive starts. India, as a nation, has a statutory regime in place and the

said regime is followed scrupulously as pointed out hereunder in detail.

(d) The Petitioner was a member of a group of experts called National Technical Advisory Group on Immunisation ("**NTAGI**") which group consists of qualified epidemiologists, infectious disease experts and clinical trialists and others and is, therefore, fully aware of the protocol in the form of a statutory regime.

(e) The country started one of the largest vaccination preparations in the world with most adverse circumstances, like different educational levels of the citizens, the effect of pandemic at its peak which posed its own challenges in vaccination etc. and initial vaccine hesitancy. The vaccines which have undergone the statutory regime and are safe were required to be administered to each and every individual in the country not only in his / her interest but also in larger public interest.

(f) The Government of India and Governments of the States, therefore, started a massive drive to inform and educate people to get themselves vaccinated. This largest vaccination drive in the world successfully gained momentum with joint

efforts of all in one and more than hundreds of crores of vaccinations have already been administered.

(g) Any misgivings and misconceived doubts and motivated propaganda against vaccination can only result into a potential threat of setting vaccine hesitancy again, which will not be in public interest. Once it is placed before this Hon'ble Court that –

(i) there is a statutory regime in place; and

(ii) the regime is followed;

this Hon'ble Court, may not undertake the exercise any further as it would enable the petitioner and handful of others like him to create serious misgivings and misconceived doubts against the vaccination in the process of this petition itself.

5. At this juncture, the entire concentration of the Central Government and the State Governments should be and is on vaccination drive and encouraging people to get them vaccinated. It is, therefore, not desirable at this juncture to invest time finding out motives behind few elements attempting to act against the interest of nation at

the cost of violating the right of crores of citizens to be protected from pandemic.

6. At the further outset, it is respectfully submitted that the subject matter of the present petition is vaccination at a crucial juncture, when a sudden pandemic has engulfed the world. Once it is pointed out that a statutory regime exists for certification and permission to administer any drug / vaccine, this Hon'ble Court would not exercise its power of judicial review for the purpose of taking any other possible view as such examination would be out of the scope of the judicial review. The petitioner cannot, under the garb of a petition under Article 32 of the Constitution, pray before this Hon'ble Court to sit in appeal over a scientific process undertaken by the domain experts and take a different view on a subject which is not the subject of expertise of any judicial forum.

7. The Petitioner is fully aware of the facts narrated hereunder. He has chosen to give a false picture before this Hon'ble Court for the reasons best known to him. In the process, however, he has raised a false alarm and warning against efforts of the nation to combat an unprecedented tragedy faced by human race. Such an attempt is to be viewed very seriously at a time when the Central Government, all State Governments and Union Territories are individually and collectively making all possible efforts

to vaccinate every individual. This Hon'ble Court may, therefore, be pleased to dismiss this petition as not maintainable, hit by principles of suppression of material facts and the subject matter being outside the scope of judicial review with exemplary costs.

8. It is submitted that, the Petitioner has approached this Hon'ble Court seeking the following reliefs, *inter alia*:-

> "*…a) Direct the respondents to release the entire segregated trial data for each of the phases of trials that have been undertaken with respect to the vaccines being administered in India; and*
>
> *…b) Direct the respondent no.2 to disclose the detailed minutes of the meetings of the Subject Expert Committee and the NTGAI with regard to the vaccines as directed by the 59th Parliamentary Standing Committee Report and the members who constituted the committee for the purpose of each approval meeting; and*
>
> *…c) Direct the respondent no.2 to disclose the reasoned decision of the DCGI granting approval or rejecting an application for emergency use authorization of vaccines and the documents and reports submitted to the DCGI in support of such application; and*
>
> *…d) Direct the respondents to disclose the post vaccination data regarding adverse events, vaccinees who got infected with Covid, those who needed hospitalization and those who died after such infection post vaccination and direct the respondents to widely publicize the data collection of such adverse event*

through the advertisement of toll free telephone numbers where such complains can be registered; and

…e) Declare that vaccine mandates, in any manner whatsoever, even by way of making it a precondition for accessing any benefits or services, is a violation of rights of citizens and unconstitutional; and

…f) Pass any other orders as this Hon'ble Court deems fit…"

9. It is submitted that, the Drugs and Cosmetics Act 1940 is a central legislation, that regulates the import, manufacture, distribution and sale of drugs and cosmetics in the country. The main objective of the Drugs and Cosmetics Act, 1940 is to ensure that the drugs available to the people are safe and efficacious and conform to prescribed quality standards and that the cosmetics marketed are safe for use.

10. The Ministry of Health and Family Welfare has made New Drugs and Clinical Trials Rules, 2019 (hereafter as "***Rules of 2019***") published in G.S.R.227 (E) dated 19.03.2019 under the Drugs and Cosmetics Act, 1940. It is submitted that, the Rules of 2019 came into effect from 19.03.2019 and substituted relevant parts of the Drugs and Cosmetics Rules, 1945.

A True copy of the New Drugs and Clinical Trials Rules, 2019 is annexed herewith and marked as **ANNEXURE R/1** at pg. **59-176.**

11. It is submitted that, as per the statutory regime contained in the provisions of the Rules of 2019, clinical trials and permission to import or manufacture New Drugs including Vaccines are granted by Central Licensing Authority i.e. Drugs Controller General ("**CDSCO**").

12. Under the Rules of 2019, the first, second and third schedule have details regarding "*general principles and practices for clinical trial*", "*requirements and guidelines for permission to import or manufacture of new drug for sale or to undertake clinical trial*" and "*conduct of clinical trial*" respectively.

13. For the present purpose, the Second Schedule to the Rules of 2019 are relevant, which as stated above, provides the requirements and guidelines for permission to import and / or manufacture new drugs for sale or to undertake clinical trials in the country.

14. Under the Second Schedule, an applicant is required to make an application for grant of permission to import and / or manufacture new drugs for sale or to undertake clinical trials (in the present case for Covid-19 vaccines) accompanied with data in accordance with the Rules of 2019. This data includes animal toxicity data, clinical data,

Chemistry Manufacturing Control (CMC) data and other relevant information.

15. The applications for grant of permission to conduct clinical trials and permission to import or manufacture new drugs (here, COVID-19 vaccines) are evaluated by the CDSCO in consultation with Subject Expert Committee "**SEC**" consisting of domain experts, which comprises of medical experts from Microbiology, Pulmonology, Immunology, Paediatrics, Internal medicine etc.

16. It is submitted that, provisions of the Second Schedule to the Rules of 2019 which were exercised to examine grant / refusal of approval to Covid-19 vaccines is reproduced below. These provisions provide for relaxation, abbreviations, omission or deferment of data for a new drug.

> **"...**
>
> ***...(2) Special situations for a new drug where relaxation, abbreviations, omission or deferment of data may be considered***. –
>
> *(i) Depending on categories and nature of new drugs to be imported or manufactured for sale or clinical trial to be undertaken (viz. New Chemical Entity, biological products, similar biologics, approved new drug or new dosage form or new indication or new route of administration or new strength of already approved drugs, etc.,) requirements of chemical and pharmaceutical information, animal*

pharmacology and toxicology data, clinical data may differ. The requirements may also differ depending on the specific phase of clinical trial proposed to be conducted as well as clinical parameters related to the specific study drug.

(ii) For drugs intended to be used in life threatening or serious disease conditions or rare diseases and for drugs intended to be used in the diseases of special relevance to Indian scenario or unmet medical need in India, disaster or special defence use e.g. haemostatic and quick wound healing, enhancing oxygen carrying capacity, radiation safety, drugs for combating chemical, nuclear, biological infliction etc., following mechanism may be followed to expedite the development of new drug and approval process.

(A) Accelerated Approval Process: *Accelerated approval process may be allowed to a new drug for a disease or condition, taking into account its severity, rarity, or prevalence and the availability or lack of alternative treatments, provided that there is a prima facie case of the product being of meaningful therapeutic benefit over the existing treatment.*

(a) In such case, the approval of the new drug may be based on data generated in clinical trial where surrogate endpoint shall be considered rather than using standard outcome measures such as survival or disease progression, which are reasonably likely to predict clinical benefit, or a clinical endpoint. These should be measurable earlier than irreversible morbidity or mortality (IMM) and reasonably likely to predict clinical benefit.

(b) After granting accelerated approval for such drug, the post marketing trials shall be required to validate the anticipated clinical benefit.

(c) Accelerated approval may also be granted to a new drug if it is intended for the treatment of a serious or life-threatening condition or disease of special relevance to the country, and addresses unmet medical needs. This provision is intended to facilitate and expedite review of drugs so that an approved product can reach the therapeutic armamentarium expeditiously.

(d) If the remarkable efficacy is observed with a defined dose in the Phase II clinical trial of investigational new drug for the unmet medical needs of serious and life threatening diseases in the country, it may be considered for grant of marketing approval by the Central Licencing Authority based on Phase II clinical trial data. In such cases, additional post licensure studies may be required to be conducted after approval to generate the data on larger population to further verify and describe the clinical benefits, as per the protocol approved by the Central Licencing Authority.

(e) The type of information needed to demonstrate the potential of a drug to address an unmet medical need will depend on the stage of drug development. Early in development, such potential should be sufficiently demonstrated based on nonclinical models, a mechanistic rationale and pharmacologic data. Later in development, prior to new drug approval such potential should be demonstrated through clinical data to address an unmet medical need.

Explanation. - For the purpose of this clause, an unmet medical need is a situation where treatment or diagnosis of disease or condition is not addressed adequately by

available therapy. An unmet medical need includes an immediate need for a defined population (i.e., to treat a serious condition with no or limited treatment) or a longer-term need for society (e.g., to address the development of resistance to antibacterial drugs).”

17. Applying the aforesaid provisions of the Second Schedule, the CDSCO, in detailed consultation and deliberation with the SEC and after examining the efficacy etc. of the vaccine and its effects granted permission for restricted emergency use of COVAXIN and COVISHIELD vaccines of Bharat Biotech International Ltd. and Serum Institute of India Ltd. respectively under the Accelerated Approval Process.

I. DETAILS AND PROCEDURE FOR CONSIDERATION APPROVAL

18. The details which can be placed in public domain and the procedure followed for scientifically considering grant or refusal of the approval given to Bharat Biotech and Serum Institute respectively are given below:

A. DETAILS OF APPROVAL OF COVID-19 VACCINE [BRAND NAME: COVAXIN] OF BHARAT BIOTECH INTERNATIONAL LIMITED APPROVED FOR RESTRICTED USE IN EMERGENCY SITUATION.

(i) ***Name of Vaccine:*** Whole Virion Inactivated Corona Virus Vaccine

(ii) ***Qualitative and Quantitative Composition:*** Each single human dose (0.5 mL) contains: Whole Virion Inactivated Corona Virus Antigen 6 micrograms produced using a Vero cell-based platform that propagates the virus, expressing the viral spike (S) protein of SARS-CoV-2.

(iii) ***Route of Administration:*** Intra Muscular (IM)

(iv) ***Indications:*** For active immunization to prevent COVID-19 caused by SARS-CoV-2 virusin individuals 18 years of age and older. The use of this vaccine should be in accordance with the official recommendation. This vaccine is permitted for restricted use in emergency situation in Clinical Trial mode, as per provisions of New Drugs and Clinical Trials Rules, 2019 under Drugs & Cosmetics Act, 1940.

(v) ***Dose:*** Two doses on Day 0 and Day 28.

(vi) ***Process followed:***

a. In light of the urgent need emerging due to the COVID 19 pandemic in the country and to have earlier availability of vaccine, the CDSCO in detailed consultation and deliberations with SEC granted

permission to Bharat Biotech for conducting Phase I/II clinical trial of Whole Virion Inactivated Corona Virus Vaccine (COVAXIN) on 29.06.2020 & Phase III clinical trial on 23.10.2020.

b. The trials were registered on www.ctri.nic.in website as prescribed in the conditions for clinical trial permission.

A True copy of Clinical Trial Permissions and CTRI Registry is annexed herewith and marked as **ANNEXURE R/2** at pg. **177-189**.

c. Bharat Biotech then submitted interim safety and immunogenicity data of Phase I and II clinical trial carried out in the country along with safety data including Serious Adverse Events (SAE) data of the ongoing Phase III clinical trial in the country.

d. As per the interim report, in Phase I trial, 375 subjects of age ≥18 to ≤55 years were enrolled across the three groups and received three vaccine formulations, BBV152A (3µg with Algel-IMDG (Aluminium hydroxide gel- Imidazoquinolingall amide (IMDG); a TLR 7/8 agonist), BBV152B (6µg with Algel-IMDG), and BBV152C (6µg with Algel).

e. Among the 375 subjects who were administered the 1st dose, a total of 79 adverse events were recorded. Among the 368 subjects who were administered the 2nd dose, a total of 15 adverse events were recorded.

f. One serious adverse event was reported after the 1st dose which resulted in hospitalization due to Viral Pneumonitis.

g. Majority of the adverse events were either mild or moderate in severity. Pain at the injection site was the most commonly reported adverse event. These adverse effects were resolved without any sequelae and majority of adverse events, i.e. about 77.35% were resolved within 1 day.

h. The other commonly reported adverse events were headache, fever, pain at the injection site, followed by headache, fatigue, and fever.

i. The adverse events were seen in a total of 51 volunteers, which is about 13.6% of the volunteers.

j. For immunogenicity, both humoral and cell-mediated responses were observed. SARS-CoV-2 Antibody Responses (Anti S1, RBD, and N IgG) post 14 days after second dose along with IgG1/IgG4 ratio along

with spot-forming cells [SFCs], antigen-specific CD3+, CD4+, and CD8+Tcells (producing IFN-γ) were submitted by Bharat Biotech.

k. None of the participants had detectable neutralizing antibodies at baseline analyzed by MNT50.

l. The proportion of participants seroconverted post 2 weeks after 2nd dose were 87.9%, 91.9%, and 82.8% in the BBV152A, B, and C groups, respectively.

m. In Phase II trial, 380 subjects of age ≥12 to ≤65 years were enrolled among two groups and received two vaccine formulations, BBV152 A and BBV152B.

n. Among the 380 subjects, who were administered the 1st dose, a total of 51 adverse events were recorded, and after administering the 2nd dose, a total of 46 adverse events were recorded.

o. No serious adverse event was reported in Phase II study.

p. All the 97 adverse events were either mild or moderate in severity. Pain at the injection site was the most common reported adverse event. The other common adverse events reported were headache,

fever and rash. Most of the adverse effects being mild in nature were resolved without any sequelae and majority of adverse events about 86% resolved within 1 day. These 97 adverse events were reported in 65 volunteers, which is about 15.4% of the total volunteers.

q. Humoral responses measured by ELISA and Neutralization assays were also observed.

r. In Phase II clinical trial, SARS-CoV-2 Antibody Responses (Anti S1, RBD, and N IgG) post 14 days after second dose was evaluated. None of the participants had detectable neutralizing antibodies at baseline analyzed by MNT50. The proportion of seroconverted participants of Group 1 and Group 2, post 4 weeks of 2nd dose was 88.0% and 96.6% respectively.

s. The data was reviewed by CDSCO in consultation with SEC, comprising of eminent experts from Microbiology, Pulmonology, Immunology, Pediatrics, Internal medicine etc. in meetings dated 09.12.2020, 30.12.2020 and 02.01.2021. The SEC noted that the vaccine Inactivated Whole Virion and this Corona Virus Vaccine had the potential to target mutated corona virus strains.

t. The data generated till then demonstrated a strong immune response (both antibody as well as T cell) and in-vitro viral neutralization.

u. The ongoing clinical trial was a large trial on 25,800 Indian subjects in which already 22,500 subjects had been enrolled including subjects with co-morbid conditions as well those which had demonstrated safety till date.

v. Moreover, Bharat Biotech presented the safety and efficacy data from non-human primate challenge study also, where the vaccine was found to be safe and effective.

w. In view of above, after detailed deliberation, the SEC recommended for grant of permission for restricted use of Covaxin in emergency situation in public interest. As an abundant precaution, the vaccine was permitted in clinical trial mode, to ensure more options for vaccinations, especially in the context of an emerging threat of mutant strains.

x. Further, it was recommended that Bharat Biotech should continue the on-going Phase III clinical trial and submit data emerging from the trial as and when available.

y. Hence, after sufficient examination, CDSCO decided to accept the recommendations of the SEC and accordingly, permission was granted to Bharat Biotech to manufacture Whole Virion Inactivated Corona Virus Vaccine (COVAXIN) for restricted use in emergency situation in clinical trial mode with various conditions/restrictions on 03.01.2021.

It is respectfully submitted that all the above scientific steps of analysing scientific data were taken as per prescribed protocol and by bodies having domain expertise.

A True Copy of new drug permission is annexed herewith and marked as **ANNEXURE R/3** at pg. **190-191.**

z. In parallel, Bharat Biotech continued its Phase III clinical trial - a randomized, double-blind, phase 3 study, to evaluate the Efficacy, Safety and Immunogenicity of Whole-Virion Inactivated SARS-CoV-2 Vaccine in 25,800 Volunteers aged 18 years and above having approximate study duration of 12 months.

aa. The Phase 3 study followed randomized study participants for efficacy until virologically confirmed (RT-PCR positive) symptomatic COVID-19 participants which was eligible for the primary

efficacy analysis. After reaching the target number (n=130) of symptomatic COVID-19 cases, the study would continue to assess safety until the completion of the study duration.

bb. Bharat Biotech submitted the interim safety and efficacy data of phase III clinical trial of Whole Virion, Inactivated Corona Virus Vaccine (BBV152) to CDSCO which was reviewed in consultation with SEC (COVID-19) in meetings held on 08.03.2021 & 10.03.2021 respectively.

cc. The SEC noted that the firm had carried out interim analysis after 43 cases of symptomatic RT-PCR positive COVID-19 had been reported, out of which 36 were in the placebo arm and 7 in the vaccine arm.

dd. After detailed deliberation, the SEC recommended for omission of the condition of use of the Vaccine in clinical trial mode. However, it was recommended that the vaccine be continued to be used under restricted use in emergency situation condition.

ee. Further, the ongoing Phase III clinical trial should be continued as per the approved protocol and Bharat Biotech should update the prescribing information

and factsheet accordingly (under restricted use in emergency situation condition).

ff. All other conditions of the marketing authorization continued to remain the same.

gg. Accordingly, based on the recommendations of SEC, the condition "*This permission is for restricted use in emergency situation in public interest use in as an abundant precaution, in clinical trial mode*" as mentioned in the permission was amended to read as "*This permission is for restricted use in emergency situation in public interest*" by CDSCO letter dated 11.03.2021 with the condition to continue ongoing Phase III clinical trial as per approved clinical trial protocol.

hh. Subsequently, Bharat Biotech submitted updated interim safety & efficacy data of Phase III clinical trial of Whole Virion Inactivated SARS-CoV-2 Vaccine (BBV152) which was reviewed by CDSCO in consultation with SEC on 22.06.2021, wherein the SEC noted that the firm submitted safety & efficacy data till two months after the second dose along with final efficacy analysis after accrual of 130 cases of symptomatic RT-PCR positive COVID-19 as required to meet the primary endpoint.

ii. Out of 130 cases, 106 were reported in the placebo arm and 24 in the vaccine arm giving vaccine efficacy of 77.8%. The Committee also noted that currently Phase III clinical trials were ongoing.

jj. After detailed deliberation, the SEC recommended that the vaccine should be continued to be used under restricted use in emergency situation and the Phase III clinical trial should be continued as per the approved protocol. It was also recommended that the firm should update the prescribing information and factsheet accordingly and submit to CDSCO for approval.

kk. As per the information available, Phase I and Phase II clinical trial reports of Bharat Biotech are published in The Lancet Infectious Diseases Journal which is publicly available. M/s Bharat Biotech vide e-mail dated 06.07.2021 also informed that phase III trial publication titled '*Efficacy, safety, and lot to lot immunogenicity of an inactivated SARS-CoV-2 vaccine (BBV152): a double-blind, randomised, controlled phase 3 trial*' was submitted to LANCET Journal on 02.07.2021.

A True copy of publications and manuscript of Phase III trial of Bharat Biotech is annexed herewith and marked **ANNEXURE R/4** at pg. **192-246.**

(vii) Further, the summary of clinical trials of Whole Virion Inactivated Corona Virus Vaccine (COVAXIN) is available in Summary of Product Characteristics (SmPC), Factsheet, prescribing Information submitted by Bharat Biotech at the time of grant of permission at www.cdsco.gov.in website.

A True copy of Factsheet and Summary of product Characteristics (SmPC) COVAXIN Vaccine is annexed herewith and marked as **ANNEXURE R/5 at** pg. **247-262.**

(viii) Further, while issuing the permission for restricted emergency use on 03.01.2021, Bharat Biotech was directed to upload updated Summary of Product Characteristics (SmPC), Factsheet, prescribing Information/ package insert on its website.

It is respectfully submitted that all the above scientific steps of analysing scientific data were taken as per prescribed protocol and by bodies having domain expertise.

B. DETAILS OF THE APPROVAL OF CHADOX1 NCOV-19 CORONA VIRUS VACCINE (RECOMBINANT) (COVISHIELD), MANUFACTURED BY SERUM INSTITUTEOF INDIA LTD. IN INDIA

FOR RESTRICTED USE IN EMERGENCY SITUATION ARE SUBMITTED AS BELOW:

(i) ***Name of Vaccine:*** ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant)

(ii) ***Qualitative and Quantitative Composition:*** One dose (0.5 ml) contains: ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant) 5×10^{10} viral particles (vp) Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike (S) glycoprotein. Produced in genetically modified human embryonic kidney (HEK) 293 cells. This product contains genetically modified organisms (GMOs).

(iii) ***Route of Administration:*** Intra Muscular (IM)

(iv) ***Indications:*** For active immunization of individuals of ≥18 years old for the prevention of corona virus disease (COVID-19) when administered in two doses schedule. The second dose should be administered between 4 to 6 weeks after the first dose. However, there is data available for administration of the second dose up to 12 weeks after the first dose from the overseas studies.

(v) ***Process:***

a. Serum Institute developed ChAdOx1 nCOV-19 Corona Virus Vaccine (Recombinant) vaccine in collaboration with Oxford University & AstraZeneca under technology transfer. Being a technology transfer vaccine of Oxford/AstraZeneca, Serum Institute had conducted Phase II/III clinical trial in the country as the clinical development including Phase I trial was conducted in other countries.

b. In light of urgent need due to COVID-19 pandemic in the country and to have earlier availability of vaccine, CDSCO in consultation with SEC granted permission to Serum Institute to conduct Phase II/III clinical trial of ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant) on 02.08.2020.

A True copy of clinical trial permission and CTRI registry is annexed herewith and marked as **ANNEXURE R/6** at pg. **263-287.**

c. Serum Institute submitted the safety, immunogenicity & efficacy data of Phase II/III clinical trials of AstraZeneca vaccine carried out in UK, Brazil and South Africa along with the safety & immunogenicity data from the ongoing Phase II/III clinical trial in the country.

d. The SEC reviewed the proposal of restricted emergency use along with above details in its meetings dated 09.12.2020, 30.12.2020 and 01.01.2021 as well as continuously reviewed the data as and when received.

e. The Medicines and Healthcare Products Regulatory Authority (MHRA), United Kingdom's approval for AstraZeneca vaccine on 30.12.2020 along with its conditions/restrictions was also reviewed by the Committee.

f. Phase II/III clinical trial of Serum Institute was observer-blind, randomized, controlled study to determine the safety and immunogenicity of COVISHIELD as compared to Oxford vaccine & Placebo in 1600 healthy Indian adults with approximate follow up of 6 months.

g. In this trial, as on 14.12.2020 (cut-off date for marketing authorization permission by Serum Institute), all 1600 participants had received first dose and 1577 participants had received second dose. Overall, the incidence of solicited reactions (injection site reactions such as pain, tenderness, redness, warmth, itch, swelling and

induration; and systemic reactions include fever, chills, fatigue, malaise, headache, arthralgia and myalgia), unsolicited adverse events and serious adverse events (SAEs) was comparable in the study and control groups. No causally related SAE was reported with the study vaccine.

h. At the time of approval, in its Phase II/III trial, Serum Institute evaluated SARS CoV-2 S-binding antibody response of COVISHIELD vaccine and data of 186 participants (140 subjects of COVISHIELD vaccine group and 46 subjects of Oxford/AZ-ChAdOx1 nCoV-19 vaccine group) post 28 days after second dose was submitted in the interim report wherein the Geometric Mean Titres (GMT) for Anti-S IgG antibodies were reported as 33331.6 in COVISHIELD vaccine and 33263.6 in Oxford/AZ-ChAdOx1 nCoV-19 vaccine group respectively with 100% seroconversion rates.

i. As per the efficacy and immunogenicity data from the overseas studies, COVID-19 Vaccine AstraZeneca efficacy against COVID-19 was reported to be 70.42% against COVID-19 cases and overall Geometric Mean Titers (GMT) of

SARS CoV-2 S-binding antibody response to COVID-19 Vaccine AstraZeneca, 28 days after second dose was reported to be 29034.74.

j. The SEC noted that the safety & immunogenicity data presented by the firm from the Indian study was comparable with that of the overseas clinical trial data.

k. Considering the seriousness of COVID-19 pandemic and the emergent situation, there was an urgent need of vaccine in the country. After detailed deliberation, SEC recommended for grant of permission for restricted emergency use of the vaccine subject to various regulatory provisions including with various conditions/restrictions.

l. After adequate examination, CDSCO decided to accept the recommendations of the SEC and accordingly, permission was granted to Serum Institute to manufacture ChAdOx1 nCOV-19 Corona Virus Vaccine (Recombinant) (COVISHIELD) for restricted use in emergency situation with various conditions/restrictions on 03.01.2021.

A True Copy of New Drug Permission is annexed herewith and marked as **ANNEXURE R/7** at pg. **288-289.**

It is respectfully submitted that all the above scientific steps of analysing scientific data were taken as per prescribed protocol and by bodies having domain expertise.

(vi) As per the information available, AstraZeneca has published the results of Safety and Efficacy data of overseas clinical trials of ChAdOx1 nCOV-19 Corona Virus Vaccine (Recombinant) in Lancet journal which is publicly available.

A True copy of publication of M/s AstraZeneca is annexed herewith and marked as **ANNEXURE R/8** at pg. **290-302.**

(vii) The summary of overseas and Phase II/III clinical trial of nCOV-19 Corona Virus Vaccine (Recombinant) conducted in the country is available in Summary of Product Characteristics (SmPC), Factsheet, prescribing Information submitted by Serum Institute, at the time of marketing authorization approval which are available on www.cdsco.gov.in website.

(viii) While issuing marketing authorization permission on 03.01.2021, Serum Institute was directed to upload updated Summary of Product Characteristics (SmPC), Factsheet, prescribing Information/ package insert on its website.

A True copy of Factsheet and Summary of product Characteristics (SmPC) COVISHIELD Vaccine is annexed herewith and marked as **ANNEXURE R/9** at pg. **303-322.**

It is respectfully submitted that all the above scientific steps of analysing scientific data were taken as per prescribed protocol and by bodies having domain expertise.

19. Therefore, it is submitted that approval to Covaxin and Covishield vaccines has been granted for restricted emergency use after following the procedure prescribed under Rules of 2019 and the Drugs and Cosmetics Act, 1940 and after detailed deliberations among eminent scientific experts, taking all precautions necessary, considering the Covid-19 pandemic. Therefore, all allegations and apprehensions raised by the Petitioner in its writ petition should be rejected based on the aforesaid submissions.

II. ***CLINICAL TRIALS & CLINICAL TRIAL DATA***

20. It is submitted that, Rule 25 of New Drugs and Clinical Trials Rules, 2019 provides various conditions of permission for conduct of clinical trial wherein, as per sub clause (v) clinical trial shall be registered with the Clinical Trial Registry of India maintained by the Indian Council of Medical Research before enrolling the first subject for the trial. As per subclause (vi) of Rule 25, clinical trial shall be conducted in accordance with the approved clinical trial protocol and other related documents and as per requirements of Good Clinical Practices (GCP) Guidelines and the provisions of Rules of 2019.

21. It is submitted that as provided by Rule 25(v), all clinical trials conducted in India are registered with the Clinical Trials Registry- India ("**CTRI**"), which is hosted at the ICMR's National Institute of Medical Statistics. This is a free and online public record system for registration of clinical trials being conducted in India and is readily accessible for public on its website www.ctri.nic.in. The Petitioner ought to have placed these facts on record.

22. Similarly, as provided under Rule 25(vi), the Expert Committee set up by CDSCO in consultation with clinical experts has formulated the Good Clinical Practices

Guidelines for generation of clinical data on drugs [hereinafter referred to as 'the Guidelines']

A True copy of the Good Clinical Practices for Clinical Research in India is annexed herewith and marked as **ANNEXURE R/10** at pg. **323-410.**

23. In the Guidelines, under subheading "2.4 Ethical & Safety Considerations", there is a specific subheading "2.4.1 Ethical Principles". The ethical principles identify the principles of privacy and confidentiality as an important principle for clinical trials and state:

> ***"d. Principles of privacy and confidentiality*** *whereby, the identity and records of the human subjects of the research or experiment are as far as possible kept confidential; and that no details about identity of said human subjects, which would result in the disclosure of their identity, are disclosed without valid scientific and legal reasons which may be essential for the purposes of therapeutics or other interventions, without the specific consent in writing of the human subject concerned, or someone authorized on their behalf; and after ensuring that the said human subject does not suffer from any form of hardship, discrimination or stigmatization as a consequence of having participated in the research or experiment."*

24. Further, the Guidelines in Para 2.4.4. prescribe "Essential Information on Confidentiality for Prospective Research Subjects Safeguarding Confidentiality", which is extracted below :

> ***"2.4.4. Essential Information on Confidentiality for Prospective Research Subjects***
> ***Safeguarding Confidentiality*** *- The investigator must safeguard the confidentiality of research data, which might lead to the identification of the individual subjects. Data of individual subjects can be disclosed only in a court of law under the orders of the presiding judge or in some cases may be required to communicate to drug registration authority or to health authority. Therefore, the limitations in maintaining the confidentiality of data should be anticipated and assessed."*

25. In addition to the above, Chapter III of the Rules of 2019 refer to Ethics Committee for Clinical Trial, Bioavailability and Bioequivalence Study. Chapter III specifies the Requirements, Constitution, Registration, Validity, Renewal of registration, proceedings, maintenance of records, suspension and cancellation. The functions of the Ethics Committee are prescribed under Rule 11 and they include safeguarding the rights, safety and wellbeing of trial subjects in accordance with the rules. These Rules also empower the Ethics Committee to discontinue or suspend the clinical trial in case it concludes that the trial is likely to compromise the right, safety or wellbeing of the trial subject.

26. In addition, ICMR has published National Ethical Guidelines for Biomedical and Health Research involving human participants. These guidelines are applicable to all

biomedical, social and behavioral science research for health conducted in India involving human participants and is revised from time to time to incorporate new developments in the field of science and technology. The latest guideline has been revised and published in the year 2017.

27. As per the National Ethical Guidelines of ICMR, there are four basic ethical principles for conducting biomedical and health research – (i) respect for persons (autonomy), (ii) beneficence, (iii) non-malfeasance and (iv) justice. These four ethical principles been enunciated for protecting the dignity, rights, safety and well-being of research participants. These four basic principles have been expanded into 12 general principles which are to be applied to all biomedical, social and behavioral science research for health involving human participants. The principles are :-

(i) Principle of essentiality

(ii) Principle of voluntariness

(iii) Principle of non-exploitation

(iv) Principle of social responsibility

(v) Principle of ensuring privacy and confidentiality

(vi) Principle of risk minimization

(vii) Principle of professional competence

(viii) Principle of maximization of benefit

(ix) Principle of institutional arrangements

(x) Principle of transparency and accountability

(xi) Principle of totality of responsibility

(xii) Principle of environmental protection

28. Under Paragraph No. 1.1.5 of the National Ethical Guidelines of ICMR, "*Principle of ensuring privacy and confidentiality*" state :

> ***"1.1.5 Principle of ensuring privacy and confidentiality*** *whereby to maintain privacy of the potential participant, her/his identity and records are kept confidential and access is limited to only those authorized. However, under certain circumstances (suicidal ideation, homicidal tendency, HIV positive status, when required by court of law etc.) privacy of the information can be breached in consultation with the EC for valid scientific or legal reasons as the right to life of an individual supersedes the right to privacy of the research participant."*

29. Similarly, under Paragraph No. 2.3 of the National Ethical Guidelines of ICMR titled as "Privacy and Confidentiality", subheading no. 2.3.3 and 2.3.6 provide :

> *"2.3.3 Any publication arising out of research should uphold the privacy of the individuals by ensuring that photographs or other information that may reveal the individual's identity are not published. A specific re-consent would be required for publication, if this was not previously obtained.*
>
> *…*
>
> *2.3.6 Data of individual participants/community may be disclosed in certain circumstances with the*

permission of the EC such as specific orders of a court of law, threat to a person's or community's life, public health risk that would supersede personal rights to privacy, serious adverse events (SAEs) that are required to be communicated to an appropriate regulatory authority etc."

30. Further, the World Medical Association has developed the "Declaration of Helsinki" as statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. These include research on identifiable human material or identifiable data.

31. The latest statement adopted in 64th WMA General Assembly, Fortaleza, Brazil, October 2013 states, *inter alia* :

- *Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.*
- *In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.*
- *Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.*

32. Paragraph No. 24 "Privacy and Confidentiality" of the Declaration of Helsinki, 2013 states :

"24. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information".

33. It is submitted that, Paragraph No. 35 and 36 "Research Registration and Publication and Dissemination of Results" of the Declaration of Helsinki, 2013 provides:

"35. every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.

36. Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication".

34. It is also submitted that Paragraph 1 (1.1) (vii) of Table 3 of Third Schedule of Rules of 2019 provide for "Informed Consent", wherein it has been provided that confidentiality of records identifying the subject would be maintained. Further, under Paragraph no. 2 (iii) of Table 3 of Third Schedule of the Rules of 2019 provide for "Informed

Consent" and this prescribes an informed consent form in which the Subject/Legally Acceptable Representative gives consent, that his / her identity will not be revealed in any information released to third parties or published. Under Paragraph 7 (xii) of Table 4 of Third Schedule of the Rules of 2019 - "Undertaking by the Investigator", the investigator undertakes to maintain confidentiality of the identification of all participating study patients and assure security and confidentiality of study data.

35. The aforesaid Guidelines, Principles and Rules have been referred to submit that clinical trial data which is in breach of the aforesaid cannot be made public. However, rest of clinical trial data that ought to be made public are already available in public domain, as is also evident from the submissions made in the present reply. Any submission of the Petitioner for disclosure of clinical trial data which would be in breach of the aforesaid rules and guidelines and which would expose any information on the participants of the clinical trial must be rejected.

III. EXPERT COMMITTEE MEETINGS

36. It is submitted that the recommendations of Subject Expert Committee (SEC) of all the meetings are uploaded on the website of CDSCO from time to time and no further disclosure as is being contended is required. A True copy of

recommendations of SEC for COVAXIN and COVISHIELD vaccines is annexed herewith and marked are as **ANNEXURE R/11** at pg. **411-421.**

37. It is further submitted that the detailed minutes of NTGAI meeting are already in public domain and can be downloaded through both ICMR &MoHFW website and no further disclosure is required. (https://main.mohfw.gov.in/Organisation/Departments-of-Health-and-Family-Welfare/immunization)

IV. VACCINATION AND ADVERSE EVENT FOLLOWING IMMUNISATION SURVEILLANCE SYSTEM IN INDIA

38. It is submitted that, the COVID 19 vaccination campaign was started in India on 16.01.2021. In the initial phase, the vaccines were offered to priority groups based on exposure and susceptibility to the COVID 19 disease. Therefore, it was initially provided to healthcare workers (16.01.2021) and frontline workers (01.02.2021), followed by the elderly (ages greater than 60 years of age) and people aged above 45 with co-morbidities from 01.03.2021 onwards. In the 3rd phase, from 01.04.2021, the population eligible to receive vaccines was expanded to include all people above 45 years of age. From 01.05.2021, all adults more than 18 years of age were eligible to receive vaccines. For lactating women, vaccination was allowed from 19.05.2021 and for pregnant women, from

02.07.2021. A True copy of the Revised Guidelines for Implementation of National Covid-19 Vaccination Program is annexed herewith and marked as **ANNEXURE R/12** at pg. **422-425.**

39. It is submitted that, the procedures and protocols for adverse event following immunization surveillance system in India are established under the National Adverse Event Following Immunisation Surveillance Guideline. The National Adverse Event Following Immunisation Surveillance Secretariat was established in the Immunization Technical Support Unit ("**ITSU**") in 2012. The National Adverse Event Following Immunisation Surveillance Secretariat had staff dedicated for managing Adverse Event Following Immunisation surveillance system. It was further strengthened by technical and subject experts from Lady Hardinge Medical College and Allied Hospitals in New Delhi which was nominated as the National Adverse Event Following Immunisation Surveillance Technical Collaborating Centre.

40. It is respectfully submitted that, under the existing National Adverse Event Following Immunisation Surveillance, there is a structure which consist of Adverse Event Following Immunisation ("**AEFI**") Committee at different levels like State and National Level, which provides guidance to the program and carries out documentation,

investigation and causality assessment besides training and orientation of health care workers and others involved in AEFI.

41. There is also an established protocol for reporting and causality assessment for any AEFI following vaccination with Universal Immunization Program (UIP) and Non-UIP vaccines.

42. The entire system of reporting AEFIs to State/ National level has been made paperless by enabling a web-based portal i.e. SAFEVAC (Surveillance and Action for Events Following Vaccination). This portal has allowed online reporting of all serious and severe adverse events following vaccinations at the district level.

43. The benefit of the web based portal is that case details are now entered, scanned copies of reports and records are uploaded and downloaded in SAFFEVAC. The portal also has facilities for generating dashboards and line-lists at different levels.

44. A similar feature for reporting of all AEFIs (including minor) by the vaccinator was made available in Co-WIN portal. At the district level, the DIOs were given the facility to report AEFI cases which have been shared with them from individuals who do not have access to Co-WIN.

Further investigations and sharing of hospital records, etc. can be done through Co-WIN by the DIO. A True copy of the Departmental Orders and Standard Operating Procedure is annexed herewith and marked as **ANNEXURE R/13** at pg. **426-427.**

45. It is humbly submitted that in order to ensure that the AEFI reporting mechanism is further strengthened, a strong convergence has been developed with the Pharmacovigilance Programme of India ("**PvPI**") under Indian Pharmacopoeia Commission ("**IPC**") for receipt of information regarding AEFI cases being reported from approximately 300 Adverse Drug Reaction Monitoring Centers in medical colleges and large hospitals throughout the country. Information from PvPI and Central Drug Control Standard Organisation (CDSCO) are collated and studied in case of any new, previously unknown events identified through AEFI surveillance.

46. The AEFI surveillance system of India successfully passed the assessment by global experts conducted by WHO in 2017 with highest possible maturity level ratings. See press release (Maximum Possible Marks to Indian NRA in WHO Assessment) dated 17 Feb 2017 under MOHFW at PIB press release archives: https://archive.pib.gov.in/archive2/erelease.aspx

A True copy of the Press Release dated 17.02.2017 is annexed herewith and marked as **ANNEXURE R/14** at pg. **428-429.**

47. It is humbly submitted that for Covid-19 vaccination, the same system of AEFI surveillance is being used. The surveillance system has been further strengthened for adult vaccination, especially for a novel vaccine which has been given only Emergency Use Authorization ("**EUA**").

48. Keeping in view the novel nature of the Covid 19 virus and adults as the target population, membership of National AEFI committee have been expanded to include Neurologists, Cardiologists, Respiratory Medicine Specialists and Medical Specialists. A True copy of the National AEFI Committee dated 08.12.2020 is annexed herewith and marked as **ANNEXURE R/15** at pg. **430-432.**

49. It is submitted that, the States/UTs have also been requested to expand the State/UT AEFI committee by including a Neurologist, Cardiologist, Respiratory Medicine Specialist, Medical Specialist and an Obstetrician-Gynecologist for strengthening AEFI surveillance for COVID 19 vaccinations. Once identified these specialists were trained on COVID-19 vaccination, AEFI surveillance and causality assessments on 08 and 09th Jan 2021.

A True copy of the Letter dated 04.01.2021 is annexed herewith and marked as **ANNEXURE R/16** at pg. **433-434.**

A True copy of the Letter dated 05.01.2021 is annexed herewith and marked as **ANNEXURE R/17** at pg. **435-436.**

50. It is submitted that, the causality assessment of AEFI cases is done at the State and National level by experts trained in causality assessment using the globally accepted causality assessment checklist, which is based on the definition and algorithm developed by WHO. Once approved by the experts of the National AEFI Committee, the results of causality assessment of AEFI cases are made available in the public domain (MOHFW website). These are shared with the States and districts for suitable action and also with the Central Drug Control Standard Organization under the Drug Controller General (India), for appropriate regulatory action.

51. In this regard, special groups have been constituted at the National level for focused causality assessments of serious and severe AEFI cases on a priority basis.

A True Copy of the Letter dated 11.02.2021 is annexed herewith and marked as **ANNEXURE R/18** at pg. **437-438.**

A True copy of the Letter dated 08.04.2021 is annexed herewith and marked as **ANNEXURE R/19** at pg. **439**.

52. The causality assessment of reported AEFI cases is a time-consuming process and hence a method of rapid review and assessment has been initiated at the National level to quickly review available information in each case and look for trends in reporting of specific events or unusual cases requiring further early investigation and assessment.

53. Besides the existing AEFI structure, a separate structure for Adverse Events of Special Interest ("**AESI**") was initiated to carry out active surveillance through sentinel sites.

V. CURRENT STATUS OF AEFI SURVEILLANCE FOR COVID 19 VACCINATION

54. It is submitted that, all cases of serious and severe AEFI [Adverse Event Following Immunisation], including reported death cases are subjected to scientific and technical review process. This process consists of rapid reviews, analysis and causality assessment done by a team of subject experts who have been trained for doing so. Only after the causality assessment has been done that the AEFI can be attributed to the vaccine. AEFI surveillance is a tool to identify and record all the possible adverse events following vaccination so that causality assessment can be done and adverse events actually caused by the vaccine

could be identified. Therefore, mere reporting of AEFI case should not be attributed to be caused by the vaccine unless proved by the causality assessment analysis.

55. It is submitted that these Adverse Event Following Immunisation is being monitored and reviewed. The percentage of such effect having serious / severe [including deaths] in case of both Covaxin and Covishield is less than 0.01%. This again is in the caveat that any such severe / serious effect including death cannot be attributed to vaccination. In all cases, it is respectfully submitted that the Central Government is conducting Rapid Review and Causality Assessment Of Serious And Severe AEFIS continuously.

VI. STATUS OF RAPID REVIEW AND CAUSALITY ASSESSMENT OF SERIOUS & SEVERE AEFIS

56. It is humbly submitted that 2116 serious and severe AEFI cases have been reported from 1,19,38,44,741 doses of COVID-19 vaccine administered till 24th Nov 2021. A report of rapid review and analysis completed for 495 (463 Covishield & 32 Covaxin) cases has been submitted. Another report of 1356 cases (1236 Covishield, 118 Covaxin & 2 Sputnik) serious and severe AEFI cases (including 495 cases already analysed) has been presented to NEGVAC. The rapid review and analysis of balance cases is underway and will be completed soon.

57. The links for information made available in public domain are mentioned below:

1- https://main.mohfw.gov.in/sites/default/files/Englishcovernote.pdf
2- https://main.mohfw.gov.in/sites/default/files/immunizationenglish30032021_0.pdf
3- https://main.mohfw.gov.in/sites/default/files/cassuliatyassesment11062021eng.pdf
4- https://main.mohfw.gov.in/sites/default/files/AEFI60casesreportenglish.pdf
5- https://main.mohfw.gov.in/sites/default/files/Englishnote.pdf
6- https://main.mohfw.gov.in/sites/default/files/aefienglish.pdf
7- https://main.mohfw.gov.in/sites/default/files/cassulityassesmentreportenglish.pdf
8- https://main.mohfw.gov.in/sites/default/files/english%20Covering.pdf
9- https://main.mohfw.gov.in/sites/default/files/englishimmunisationlist24112021.pdf

58. Some of the other relevant reports that are available in public domain are:-

Regarding report on bleeding and clotting events following COVID 19 vaccination in India with advisory:

https://www.pib.gov.in/PressReleseDetailm.aspx?PRID=1719293 – *'Bleeding and clotting events following COVID vaccination miniscule in India - National AEFI (Adverse Event Following Immunization) Committee submits report to the Union Health Ministry'* - Posted On: 17 MAY 2021 2:32PM by PIB Delhi

A True copy of the Press Release dated 17.05.2021 is annexed herewith and marked as **ANNEXURE R/20** at pg. **440-441.**

59. It is submitted that, clarification of reports of deaths following COVID 19 vaccination and process of causality assessment can be found at: https://pib.gov.in/PressReleasePage.aspx?PRID=1727196

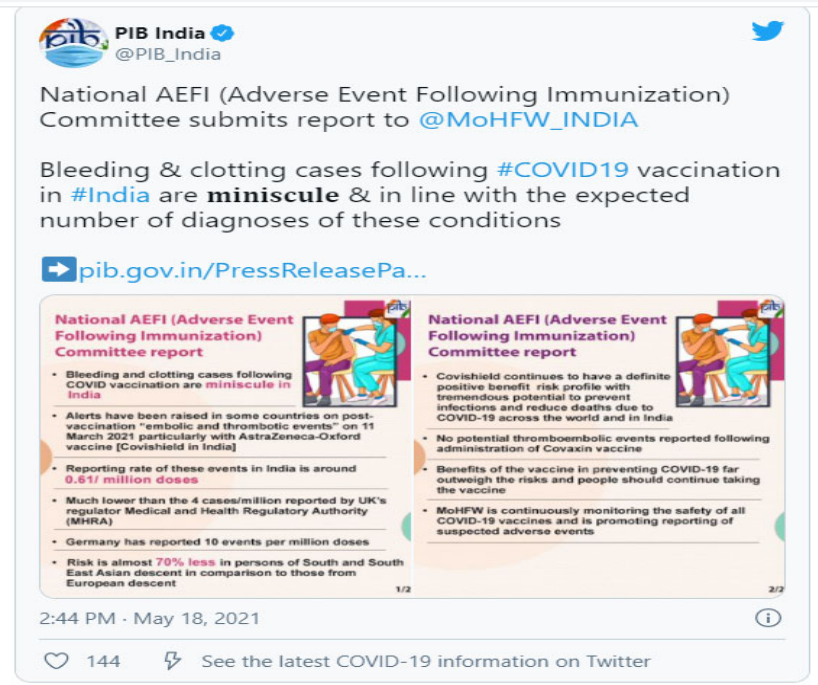
COVID19 Vaccination: Myths Vs. Facts

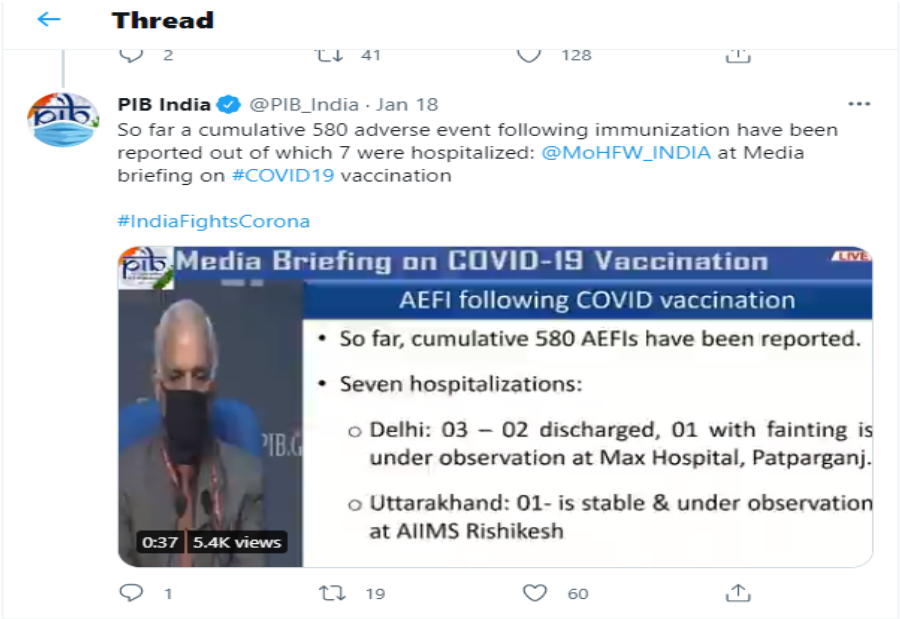
60. It is submitted that, any death or hospitalization following vaccination cannot be automatically assumed to be due to vaccination; herein, causality assessments help to understand whether the "Adverse Event Following Immunization" was caused directly due to vaccine, and are conducted at State and national level for the investigated cases - Posted On: 15 JUN 2021 2:51PM by PIB Delhi.

Tweets by PIB regarding report on bleeding and clotting events following COVID 19 vaccination in India with advisory

61. It is submitted that the following tweets highlights bleedings and clotting events following the COVID-19 vaccination in India with advisory:

https://twitter.com/pib_india/status/1394582220367560704?lang=en





A True copy of the Press Release of PIB dated 15.06.2021 is annexed herewith and marked as **ANNEXURE R/21** at pg. **442-443.**

62. Therefore, it is submitted that there is continuous monitoring and examination of AEFI cases in India and any contrary submissions made by the writ petitioner in the writ petition are denied as incorrect and without adequate knowledge of all facts.

VII. ***MANDATING USE OF VACCINES***

63. The Central Government has formulated a detailed policy document providing broad vision of government regarding Covid-19 vaccination programme, under the title "Covid-19 Vaccine Operational Guidelines". This document

is on the website of the Central Government from the date it was made. This programme takes care of the pandemic situation as on the date of this Affidavit.
https://www.mohfw.gov.in/pdf/COVID19VaccineOG111Chapter16.pdf

64. In so far as the Petitioner's submissions regarding Covid 19 vaccine being mandatory, as per the Operational Guidelines document, COVID-19 vaccination is voluntary. However, it is emphasised and encouraged that all individuals take vaccination for public health and in his / her interest as well as public interest since in case of pandemic, an individual's ill health has a direct effect on the society. Covid-19 vaccination is also not linked to any benefits or services. Therefore, any submissions made by the Petitioner to the contrary, in so far as the Answering Respondents are concerned, is denied.

VIII. INDEMNIFICATION OF VACCINE MANUFACTURERS

65. No indemnity has been granted and the current legal regime under the New Drugs and Clinical Trials Rules, 2019 and Drugs and Cosmetics Act, 1940 does not contain any such provisions.

IX. PARLIAMENTARY STANDING COMMITTEE AND CDSCO:

66. In the report of the Hon'ble Parliamentary Standing Committee (PSC) during their review of functioning of CDSCO, the PSC examined the mandate and structure of CDSCO, qualification and powers of Drugs Controller General (India) [DCG(I)], role of the State Drug Regulatory Authority, capacity building of CDSCO and Central & State Drug Testing Laboratories, Infrastructure at Airport and Sea Port, New Drugs approval, Drugs withdrawn/discarded/banned abroad but available in the country, issue of granting licences by the States on Fixed Dose Combinations without approval of DCG (I), Drug Technical Advisory Board (DTAB), issues regarding similar brand names, Post marketing surveillance, Pharmacovigilance, updation on information of marketed drugs, spurious/sub-standard drugs, advertisement of prescription drugs in lay media and consumer information and clinical trial on new drugs.

67. The Ministry of Health and Family Welfare submitted its action taken reply on the above mentioned report on 28.12.2012.

68. In the reply, the Ministry submitted the details of various steps taken to strengthen Drug Regulatory System including the measures taken to streamline the process of

New Drug approval and recommendations of Dr. Katoch Committee of experts constituted by the Ministry to examine the validity of the scientific and statutory basis adopted for the approval of New Drug without Clinical Trial pointed-out in the 59th report, etc.

69. The Hon'ble Parliamentary Standing Committee then considered the action taken replies and made various recommendations for implementation in its 66th report. Since then the matter relating to drug regulatory structures being made more efficient has been examined by a number of Committees. Necessary follow up action has been taken on the findings and recommendations of those Committees. The recommendations made by Dr. Katoch Committee were further gone into by Prof. Ranjit Roy Chaudhory Committee and various recommendations have been implemented.

70. CDSCO has since been strengthened and a number of measures have been taken to address issues, including online submission and processing of various applications under SUGAM portal, notification of Medical Devices Rules, 2017 and New Drugs and Clinical Trials Rules, 2019, guidelines for biosimilars, evaluation of applications of clinical trials, new drugs and Investigational New Drug (IND) including r-DNA derived products and vaccines, new medical devices in consultation with Subject Experts Committees, various amendments in Drugs and Cosmetics

Rules including amendment for prohibition of advertisement of Schedule H, H1 & X drugs, provisions to address issues related to similar brands, action addressing issues on FDCs, measures to ensure quality of drugs, etc. as well as strengthening of infrastructure and manpower of CDSCO.

71. Based on the aforesaid reply, it is submitted that Covaxin & Covishield vaccines clinical trials were registered at www.ctri.nic.in. Clinical Trials Registry- India (CTRI), hosted at the ICMR's National Institute of Medical Statistics, which is a free and online public record system for registration of clinical trials being conducted in India, which is readily accessible for public.

72. Procedure prescribed under the Drugs and Cosmetics Act, 1940 and Rules of 2019 were strictly followed while granting permission to Covaxin and Covishield vaccines.

73. The ICMR guidelines and Declaration of Helsinki clearly mention to maintain privacy of the potential participant; her/his identity and records are kept confidential subject to certain exceptions as stated therein.

74. Neither the Rules of 2019, nor the GCP guidelines, ICMR guidelines, Declaration of Helsinki prescribe that the publication of the clinical trial study reports of each

participating clinical trial sites is mandatory before approval of any new drugs including vaccine.

75. The Summary of Product Characteristics (SmPC), Factsheet, prescribing Information submitted by firm at the time of marketing authorization approval are available on the website of CDSCO at the URL, www.cdsco.gov.in which contains summary details of clinical trial data and results, moreover, these trials are also registered on Clinical Trial Registry of India, maintained by ICMR which contains the trial details and data in public domain.

76. The clinical data generated in a clinical trial resides with the sponsor of the clinical trial and the data is submitted to the regulatory authorities for obtaining various permissions/licenses etc. The regulatory authority may verify the veracity of the data submitted. However, there is no regulatory provisions under which the regulatory authorities can direct the sponsor to place the full clinical trial data in public domain.

77. To summarize, it is humbly submitted that all data relating to clinical trial, approval by DCGI and vaccination data that is required to be and can be released as per law is already available in the public domain. The minutes of meetings and committee deliberations to the extent permissible are already in the public domain. Decision

regarding approval of Covid 19 vaccines have been taken by expert committees consisting of domain experts based on and after verifying data / information supplied by the manufacturers and after considering its efficacy and safety. Post vaccination adverse data is already in the public domain and the concerned authorities are continuously monitoring and examining this data. The Central Government has not mandated for Covid 19 vaccines to be administered mandatorily at this stage.

78. In light of the aforesaid submissions, it is submitted that the writ petition filed by the Petitioner deserves to be dismissed.

79. The Answering Respondents reserve their right to file detailed para wise reply at an appropriate stage of the proceedings.

80. The Answering Respondents submit accordingly.

Dr. P. B. N. PRASAD
Joint Drugs Controller (I)
DEPONENT
Central Drugs Standard Control Organisation
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O., New Delhi-110002

VERIFICATION:

I, the Deponent above-named, do hereby verify the contents of the above-mentioned Affidavit as being correct to the best of my knowledge and information and state that nothing material has been kept concealed therefrom.

Verified at New Delhi on the 28th day of November, 2021.

Dr. P. B. N. PRASAD
Joint Drugs Controller (I)
DEPONENT
Central Drugs Standard Control Organisation
Dte. General of Health Services
Ministry of Health and Family Welfare
FDA Bhawan, Kotla Road, I.T.O., New Delhi-110002

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IN THE HIGH COURT OF BOMBAY AT GOA

WRIT PETITION No. 1820 of 2021

IN THE MATTER OF:

Mr. Nelson Paulo Fernandes & Another

.....Petitioners

Versus

The State of Goa & Ors.

.....Respondents

COUNTER AFFIDAVIT ON BEHALF OF ANSWERING RESPONDENT NO. 6 (MINISTRY OF HEALTH & FAMILY WELFARE, GOVT. OF INDIA)

I, Satyendra Singh, S/o Sh. Phool Singh, aged about 41 years, working as Under Secretary COVID Vaccination Administration Cell in the Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi do hereby solemnly affirm and sincerely state as follows:

1. That, I am well acquainted with the facts of the case from the records. I am filing this Counter Affidavit on behalf of the Ministry of Health & Family Welfare, Govt. of India, as I am authorized to do so.

NOTARY PUBLIC M. P. SHUKLA Regd. No. 17817 DELHI Expiry Date: 22.12.2024 GOVT. OF INDIA

08 OCT 2021

2. I have perused the Writ Petition of the petitioner and I deny the averments made therein, except those that are specifically admitted hereunder.

3. I humbly submit that, the Petitioner has filed this writ petition seeking directions predominantly as against the State Government. However, since we are also made a party, I am filing this counter affidavit.

4. That, it is humbly submitted by the Answering Respondent No. 6 that, instead of traversing various allegations para-wise, this respondent deems it appropriate to counter the whole set of the facts in this matter as follows:

It is submitted that in the Writ Petition the petitioner has prayed the interim prayer as follows: -

"1. *For an appropriate Writ, order or direction, thereby quashing the circular dated 13/07/2021 issued by respondent no. 2 (Director, Directorate of Education, Govt of Goa).*

For an appropriate Writ, order or direction, thereby directing the respondent no. 1 and 2 (State of Goa and Director, Directorate of Education, Govt of Goa) to consider the petitioner's representations dated 30/07/2021 and 11/08/2021 and to issue a corrigendum

NOTARY PUBLIC * M. P. SHUKLA Regd. No. 17817 DELHI Expiry Date: 22.12.2024 * GOVT. OF INDIA

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thereby making the vaccination by the teaching and non-teaching staff voluntary.

3. *For an interim relief, staying the operation of circulars dated 16/07/2021, 28/07/2021 and 16/08/2021 thereby directing the respondent No 2 and 3 (Headmistress, Little Flower of Jesus High School) not to take any coercive measures/actions against the petitioners pending the hearing and final disposal of petition.*

4. *For ex parte relief in terms of prayer clause 3.*

5. It is further humbly submitted that the matter has been examined and from the prayer (at para 1, 2 & 3 above) and the statements of the petitioner in the writ petition, it is evidently clear that the grievances of the petitioner in the prayer is related to the Departments of State Government of Goa (Respondent No. 1 and 2).

6. That, it is further humbly submitted that the annexures as mentioned in the Writ Petition by the petitioner have been issued by the Departments under State Government of Goa.

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7. That, it is further submitted that the subject matter of the present Petition does not fall within the domain of the Answering Respondent No. 6 (Union of India).

8. That, it is further humbly submitted that however, since this matter is related to vaccination, and Union of India is the respondent no. 6; thus, it is pertinent to present the stand of Union of India with regards to vaccination. It is humbly submitted that vaccination for Covid-19 is a matter of social obligation and is of a larger public interest. As a responsible citizen looking to contribute in the nation and humanity's fight against the Pandemic of Covid-19 infection, it is natural that every person would get her/himself vaccinated against Covid-19 so as to prevent the spread of Covid-19 infection in the community.

9. That, it is further humbly submitted that the directions and guidelines released by Government of India and Ministry of Health and family Welfare, do not entail compulsory or forcible vaccination against COVID-19 disease implying that COVID-19 vaccination is completely voluntary for all citizens of India. Ministry of Health and Family Welfare, Government of India has not formulated or suggested any policies for discrimination between

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citizens of India on the basis of their vaccination status.

10. That, it is duly advised, advertised and communicated by MoHFW through various print and social media platforms that all citizens should get vaccinated, but this in no way implies that any person can be forced to be vaccinated against her/his wishes.

11. That, as per the existing guidelines, there is no provisions for forcing any citizen to book appointment for Covid Vaccination on Co-WIN or visiting Covid Vaccination Center for vaccination. if a person above the age of 18 years visits a Covid Vaccination Centre by her/his choice for vaccination and asks for the same, it implies that she/he is voluntarily coming to the center to get the benefit of Covid Vaccination.

12. Therefore, it is humbly submitted that in order to prevent the transmission and spread of Covid-19 pandemic, it is expected that all responsible citizens especially the teachers who are also the role models and influencers for the society get themselves vaccinated as soon as possible against Covid-19 and meticulously follow Covid Appropriate Behaviour.

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13. **Prayer:**

It is therefore most humbly prayed that, this Hon'ble Court may be pleased to admit this Counter Affidavit on behalf of Answering Respondent No. 6 (Union of India) on this petition for the ends of justice.

DEPONENT

(सत्येन्द्र सिंह)
(SATYENDRA SINGH)
अवर सचिव / Under Secretary
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Ministry of Health & Family Welfare
भारत सरकार / Govt. of India
नई दिल्ली / New Delhi

Identified by

VERIFICATION:

Verified at New Delhi on October 08, 2021 that the contents of this affidavit are true and correct to the best of my knowledge and belief and no part of it is false thereof, and no material fact has been canceled therefrom.

DEPONENT

(सत्येन्द्र सिंह)
(SATYENDRA SINGH)
अवर सचिव / Under Secretary
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Ministry of Health & Family Welfare
भारत सरकार / Govt. of India
नई दिल्ली / New Delhi

NOTARY PUBLIC
M. P. SHUKLA
Regd. No. 17817
DELHI
Expiry Date: 22.12.2024
GOVT. OF INDIA

08 OCT 2021

M. P. SHUKLA
Notary Public, Delhi

CERTIFIED THAT THE DEPONENT
Shri/Smt/Km. ..... Aged .....
S/o, W/o, D/o, Sh. .....
identified by .....
has solemnly affirmed ..... Delhi
on 21/10/2021
that the contents of this affidavit ..... S/o, W/o, D/o .....
have been read & explained to him/her/them and he/she/they
CERTIFIED THAT THE DEPONENT

M. P. SHUKLA
Notary Public, Delhi

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E- FILED ON 13/1/2022

IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

WRIT PETITION (CIVIL) NO. 580 OF 2021

IN THE MATTER OF:

EVARA FOUNDATION ... PETITIONER

VERSUS

UNION OF INDIA & ORS. ... RESPONDENTS

AFFIDAVIT DATED 13.01.2022 ON BEHALF OF THE UNION OF INDIA

PAPER-BOOK

(FOR INDEX KINDLY SEE INSIDE)

ADVOCATE FOR THE UNION OF INDIA: G S MAKKER

ADVOCATE FOR THE UNION OF INDIA: G S MAKKER

IN THE SUPREME COURT OF INDIA

CIVIL ORIGINAL JURISDICTION

WRIT PETITION (CIVIL) NO. 580 OF 2021

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IN THE SUPREME COURT OF INDIA
CIVIL ORIGINAL WRIT JURISDICTION
WRIT PETITION (CIVIL) NO.580 OF 2021

EVARA FOUNDATION ...PETITIONER

VERSUS

UNION OF INDIA &ANR. ...RESPONDENTS

AFFIDAVIT DATED 13.01.2022 ON BEHALF OF THE UNION OF INDIA

I, Dr. Veena Dhawan, Wife of Dr. Puneet Dhawan, aged 56 years, working as Joint Commissioner (UIP) in the Ministry of Health & Family Welfare, Government of India, the deponent herein, do hereby solemnly affirm and state on oath as under:-

1. That I am Joint Commissioner (UIP) in the Ministry of Health & Family Welfare, Government of India ('MoHFW'). I am filing this affidavit in furtherance of this Hon'ble Court's order dated 03.12.2021 wherein this Hon'ble Court was pleased to observe as under:

"... A preliminary affidavit has been filed by the Union of India. In view of the contents of the affidavit which has been filed on behalf of

NOTARY A.N. SINGH Supreme Court of India Regn. No. 16959 Exp. Date: 31.01.2025 GOVT. OF INDIA

(डा. वीना धवन)
(Dr. VEENA DHAWAN)
संयुक्त आयुक्त (इम्यु.)
Joint Commissioner (Imm.)
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Ministry of Health & F.W.
Govt. of India

the Union of India, we grant liberty to the Petitioner to formulate any concrete suggestions which they may have to strengthen the existing framework for facilitating the vaccination of the disabled and to ensure that they have proper access to vaccination against COVID-19.

Mr. Pankaj Sinha, Counsel appearing on behalf of the Petitioner, together with other counsel appearing for the Petitioner, would, after due consultation, prepare a set of suggestions which can be emailed to the following email id: cmvc.dyc@gmail.com. A copy of the suggestions shall also be emailed to Ms. Aishwarya Bhati, Additional Solicitor General appearing on behalf of the Union of India. Once the suggestions are emailed, they would be the subject matter of further deliberations, with a view to consider if the existing framework for vaccination of the disabled needs to be suitably strengthened by incorporating additional safeguards or facilities. Ms. Aishwarya Bhati may respond to the suggestions with proposed measures."

2. That in furtherance of the above order, the Union of India received a list of suggestions from the Petitioner on 09.12.2021, which have been duly considered and the deponent is filing the present affidavit to apprise this Hon'ble Court about the steps that have been taken to address the suggestions given by the Petitioner.

NOTARY
A.N. SINGH
Supreme Court of India
Regn. No. 16959
Exp. Date : 31.01.2025
GOVT. OF INDIA

(डॉ. वीना धवन)
(Dr. VEENA DHAWAN)
संयुक्त आयुक्त (एम्यु.)
Joint Commissioner (Imm.)
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Ministry of Health & F.W.
भारत सरकार/Govt. of India

3. India's COVID-19 vaccination programme is the largest vaccination programme in the world. As on 11.01.2022, a total of 1,52,95,43,602 doses have been administered wherein, 90.84% of eligible adult population has received their first dose of the vaccine and 61% has received their second doses. Furthermore, a total of 23678 doses have been administered to disabled persons who have voluntarily chosen to be identified as such by using their Unique Disability ID Card/Disability Certificate for registration at the time of their vaccination.

PRELIMINARY SUBMISSIONS

4. At the outset, it is most respectfully submitted that India's COVID-19 vaccination drive is being guided by scientific and domain knowledge experts through a National Expert Group on Vaccine Administration for COVID-19 (NEGVAC). NEGVAC provides guidance on all aspect 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

NOTARY A.N. SINGH Supreme Court of India Regn. No. 16959 Exp. Date : 31.01.2025 GOVT. OF INDIA

(डा. वीना धवन) (Dr. VEENA DHAWAN) संयुक्त आयुक्त (इम्यु.) Joint Commissioner (Imm.) स्वास्थ्य एवं परिवार कल्याण मंत्रालय Ministry of Health & F.W. भारत सरकार/Govt. of India

evidence based and collaborative decision making that is adaptive to local needs. On technical aspects pertaining to COVID-19 vaccination, the NEGVAC is guided by the National Technical Advisory Group of Immunisation (NTAGI) which is India's apex advisory body on immunisation. The NTAGI examines the technical aspects like usage of different varieties of COVID-19 Vaccines, interval between vaccine doses, contraindications etc. and recommends the same to NEGVAC. NEGVAC in turn provides overall guidance and recommendations on all aspects of COVID-19 vaccination to MoHFW including prioritization of population groups, procurement and inventory management, vaccine selection, vaccine delivery and tracking mechanism etc.

RESPONSE TO SUGGESTIONS MADE BY THE PETITIONER

5. Helpline numbers: It is humbly submitted that this suggestion has already been implemented. The Government of India has a toll-free 24x7 national helpline number 1075 which caters to queries on COVID-19 vaccination from every individual, including those with disabilities. A Technical Helpline (0120-4473222) has also been established to specifically handle Co-WIN software

related queries. The personnel administering these helplines are aware of advisories and guidance documents issued by MoHFW in regard to differently abled people. There is also a State 104 Helpline number, which is primarily intended to provide medical assistance for several minor illnesses, ailments, and mental distresses, along with details on health schemes. The GoI has also provided guidance for augmenting the capacity of 104 Helpline for addressing queries on COVID-19 vaccination including grievance redressal related to vaccination process as well as linking to concerned facilities for management of any adverse event (available at: https://www.mohfw.gov.in/pdf/COVID19VaccineOG111Chapter16.pdf).

Further guidance has been provided by Government of India by way of letter dated 11.06.2021 for orientation of 104 helpline personnel so as to facilitate the provision of requisite information to differently abled persons so as to facilitate their proper care and vaccination.

Ref: Letter dated 11.06.2021 issued by Secretary, MoHFW at page 20 of Preliminary Affidavit dated 30.09.2021.

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Furthermore, for medical query related assistance, MoHFW has established a patient to doctor telemedicine platform. Accordingly, a National Telemedicine Service by the name of eSanjeevaniOPD (https://www.esanjeevaniopd.in/) was rolled out nationally by MohFW on 13.04.2020 in the early stage of the COVID-19 pandemic. Since then, eSanjeevaniOPD (National Telemedicine Service) has been rolled out by 30 States and around 25,000 doctors have been on-boarded on eSanjeevaniOPD. Over 531 online OPDs are functional on eSanjeevaniOPD of which over 480 are specialist and super-specialist OPDs and 51 are General OPDs. Till now 63,56,743 consultations have been effected on eSanjeevaniOPD. eSanjeevaniOPD is citizen-friendly safe medium to seek health services by citizens in the confines of their homes. In many states eSanjeevaniOPD services are available round the clock and even on holidays.

6. Door to door vaccination and other measures relating to vaccination centers: It is most respectfully submitted that suggestions in this regard have already been implemented. It is humbly submitted that guidance has been provided to States/UTs to undertake meticulous, need-based micro-planning so that Near

to Home Vaccination Centre (NHCVC) strategy is undertaken at block/urban area level and identification of NHCVC sites done as per Guidelines. The location of NHCVCs is to be done by district/urban task forces so as to ensure maximum reach of services to the eligible population.

Guidelines on NHCVC suggest utilizing of line lists already available with health or other departments (like department of Social Welfare) at state/district level. Provisions have already been made to consider scenarios where there is a group of target beneficiaries under one roof such as institutions serving differently abled people, old age homes etc; wherein the NHCVC can be organized at that site as per operational guidelines.

NHCVC Guidelines also details the steps that may be taken for making the vaccination centre friendly to the elderly and persons with special needs. The Guidelines further mention that vaccination team will facilitate on-site registration of the targeted beneficiaries in the Co-WIN portal, if they are not already registered.

States have been advised that while NHCVCs should continue to be functional, at the same time, it must also be

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ensured that other CVCs are also fully accessible to persons with disabilities as per the accessibility standards mandated under Rights of Persons with Disabilities Act 2016.

Ref: Annexure R/2 at pages 13-19 and Annexure R/4 at pages 22-23 of the Preliminary Affidavit dated 30.09.2021.

Keeping in view the need of all persons who might be bed ridden or have extremely restricted mobility or disability and/or special needs that may hamper their accessibility even to Near to Home Vaccination Centres (NHCVCs), Government of India in its letter dated 22.09.2021 has advised all States/UTs for preparing a line-list of all such potential beneficiaries and their care givers and subsequently vaccinate all such beneficiaries at their place of residence using mobile vaccination teams. Furthermore, on 03.11.2021, the Government of India launched the "Har Ghar dastak Abhiyan" campaign to ensure 100% coverage of eligible beneficiaries with first dose and vaccination of due beneficiaries with second dose of the COVID-19 vaccines. Due beneficiaries identified by the team are vaccinated on the spot or mobilized to CVC, if one is operational in close vicinity. This brings the Covid 19 vaccination to the door step of all due beneficiaries, including persons with disabilities. Spot registration of all beneficiaries and

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vaccination doses in Co-WIN in door-to-door campaigns and through mobile teams is facilitated by the vaccinators.

A true copy of letter dated 01.11.2021 for the Har Ghar Dastak Campaign is annexed herewith and marked as **ANNEXURE- R/1.**

7. **Vaccination access for persons with disabilities without ID cards**: It is most respectfully submitted that suggestions in this regard have already been implemented. Provisions have been made for persons who do not have any of the prescribed ID cards for availing Covid-19 vaccinations by following Facilitated Cohort Registration process on Co-WIN. Co-WIN system provides the facility for creation of special vaccination sessions for this purpose and these sessions will have the features of registration of as many beneficiaries as are to be covered (subject to the limit of session capacity), without mandatory capturing of Mobile Number and Photo ID Card, through facilitated cohort registration and all vaccination slots in such special sessions will be reserved for vaccination of such facilitated cohorts. It may be noted that as on 06.01.2022, a total of 58,81,979 persons without any IDs have been vaccinated under the National COVID-19 vaccination programme.

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A true copy of the SOP for COVID-19 vaccination of persons without prescribed ID cards through Co-WIN is annexed herewith and marked as **ANNEXURE – R2.**

8. **Definition of disability:** It is most respectfully submitted that the scope of the National COVID-19 vaccination programme is to vaccinate all eligible population, including all persons with different types of disabilities. For the purposes of the COVID-19 vaccination programme, the definition of disability under the Rights of Persons with Disabilities Act, 2016 and the contours thereof are immaterial.

9. **Data collection of persons with disabilities:** It is most respectfully submitted that the scope of the National COVID-19 Vaccination Programme is to facilitate self-registration and vaccination of all eligible population in the shortest possible time, taking into consideration the needs of vulnerable sections of society. The framework for data collection/recording on Co-WIN portal is decided by technical groups such as NEGVAC and NTAGI based on scientific necessity.

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10. Nodal Officers: As previously submitted in the Preliminary Affidavit dated 30.09.2021, this suggestion has already been implemented by the Government of India. It is most respectfully submitted that in its letter dated 11.06.2021, Government of India has advised that District level officer of Disability/Social Welfare department is to be considered as designated Nodal Officer for the purpose of dealing with redressal of grievances of differently abled persons in connection with COVID-19. She/he will work in close co-ordination with Chief Medical Officer of the district for the said purpose.

Ref: Annexure R/3 at pages 20-21 of Preliminary Affidavit dated 30.09.2021.

11. Information related to COVID-19 vaccination be available in accessible/disabled-friendly formats and vernacular languages: It is most respectfully submitted that the Co-WIN public interface is available in 11 regional languages in addition to English. It is also submitted that open files of awareness materials have been shared with the States for translation, publication and dissemination in any language / accessible format. It may be noted that any information pertaining

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to COVID-19 vaccination may also be sought from the multiple helplines mentioned earlier.

12. Awareness campaigns: It is most respectfully submitted that information on all aspects of COVID-19 vaccination programme is disseminated by Government of India and State/UTs through websites, print media, AV radio and television and also through other social media platforms. The Har Ghar Dastak Campaign in particular is a pan India campaign which will increase this reach even further. The Ministry has regularly promoted the National helpline number 1075 for all COVID-19 related queries.

13. Consent of persons with disabilities: It is humbly submitted that the directions and guidelines released by Government of India and Ministry of Health and Family Welfare, do not envisage any forcible vaccination without obtaining consent of the concerned individual. It is further humbly submitted that vaccination for COVID-19 is of larger public interest in view of the ongoing pandemic situation. It is duly advised, advertised and communicated through various print and social media platforms that all citizens should get vaccinated and systems and processes

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have been designed to facilitate the same. However, no person can be forced to be vaccinated against their wishes.

14. Exemption from vaccination certificates for persons with disabilities: It is most respectfully submitted that the Government of India has not issued any SOPs which make carrying of vaccination certificate mandatory for any purpose.

15. Care providers as essential workers: It is most respectfully submitted that the National COVID-19 vaccination program endeavours to vaccinate the entire eligible population in the least amount of time. As such, Government of India in its letter dated 22.09.2021 has advised all States/UTs to vaccinate bed ridden or beneficiaries with extremely restricted mobility or disability and/or special needs along with their care givers at their place of residence using mobile vaccination teams.

Ref: Annexure R/4 at page 22 of Preliminary Affidavit dated 30.09.2021.

16. Exemption from masks/face-cover: It is humbly submitted that the practice of using masks/face cover is in line with the recommendation of the W.H.O (World Health Organization) and

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other prominent public health agencies globally and is being advocated and followed universally as one of the most important methods to prevent the spread of COVID-19 infection. Asymptomatic or pre-asymptomatic infected person who may feel well and are unaware of their infectiousness to others are also likely to transmit infections to others. Similarly, persons with disabilities are just as likely to get infected with COVID-19 and transmit the same around them as any other person. In view of the same, in larger public interest, it is advisable that use of mask/face covers be universally followed.

17. Post vaccination monitoring: It is respectfully submitted that the Adverse Event Following Immunization (AEFIs) are monitored through a well-structured & robust AEFI surveillance system which has stood the test of time. As per the AEFI surveillance guidelines for COVID-19 vaccine, any suspected adverse events, following COVID-19 vaccine may be reported by any vaccine-recipient or his/her caregiver on COWIN portal through the vaccinator or the District Immunization Officer (DIO) Ref: Covid-19 Vaccine Operational Guidelines available at MoHFW website at:

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https://www.mohfw.gov.in/pdf/COVID19VaccineOG111Chapter16.pdf.

18. **Co-WIN app and portal to be fully accessible**: It is most respectfully submitted that Government of India is already implementing features in Co-WIN portal to make it more accessible to persons with disabilities as mentioned in the Preliminary Affidavit dated 30.09.2021.

19. **Counselling before vaccination:** It is humbly submitted that Government of India has formulated Operational Guidelines for COVID-19 vaccination. As per these Guidelines, all beneficiaries are to be informed about adverse events which may occur after COVID-19 vaccine.

Ref: Covid-19 Vaccine Operational Guidelines available at MoHFW website at: https://www.mohfw.gov.in/pdf/COVID19VaccineOG111Chapter16.pdf.

20. **Accountable assessment/feedback of vaccination process:** It is humbly submitted that there already exists a grievance redressal mechanism wherein all grievances received, including

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those received from persons with disabilities, are redressed in a timely manner. In addition, as mentioned earlier, nodal officers in each State have been advised to look into grievance redressal for persons with disabilities in particular.

21. The present affidavit is filed bona fide and in the interest of justice. The present affidavit is filed to apprise this Hon'ble Court on the steps taken by the Union of India in regard to issues highlighted by the Petitioner and the same may be read in conjunction with the earlier Preliminary Affidavit dated 30.09.2021 for receiving an exhaustive view on the matter.

I identify the deponent who has signed/put T.I. in my presence
MHH/433/9/2016

ATTESTED
A.N. Singh, Adv.
Notary Public
Govt. of India, Delhi
Mob.: 9718139501, 7982599115
13 JAN 2022

DEPONENT
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VERIFICATION

I, the deponent above named, do hereby verify that the contents of Para 1 to 20 of my above affidavit are prepared on the basis of instructions received by me and on the basis of legal advice received and no part of it is false and nothing material has been concealed therefrom to the best of my knowledge.

NOTARY A.N. SINGH Supreme Court of India Regn. No. 16959 Exp. Date: 31.01.2025 GOVT. OF INDIA

Verified at New Delhi on this 13 JAN 2022

Certified that the above Named Deponent identify by Shri/Smt. ...
Solemenly affarmed before me at Delhi
S. No. 3364
The contents of the affidavit which have been read & explained to me are true and correct
Notary
13 JAN 2022

DEPONENT
(डॉ. वीना धवन)
(Dr. VEENA DHAWAN)
संयुक्त आयुक्त (इम्यु.)
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P.i'ss

मिसिल संख्या जेड.60011/06/2020-सीवीएसी
भारत सरकार
स्वास्थ्य और परिवार कल्याण मंत्रालय
सीवीएसी अनुभाग

09 MAR 2021
ISSUED
MINISTRY OF HEALTH & F.W.

निर्माण भवन, नई दिल्ली
दिनांक09 मार्च, 2021

To,

Sh. Anurag Sinha,
Qtr no. 10 po swang bokaro
Jharkhand, gomia, 829128
Jharkhand

विषय: आरटीआई अधिनियम, २००५ के अंतर्गत मांगी गई जानकारी के संबंध में।

महोदय,

कृपया आप अपनी आर.टी.आई. एमओएचएफडब्ल्यू/आर/ई/21/00630, आर.टी.आई. अधिनियम, 2005 के संदर्भ ले जोकि अधोहस्ताक्षरी को दिनांक 27.02.2021 को प्राप्त हुआ था जिसमें आर.टी.आई.(RTI) अधिनियम, २००५ के तहत जानकारी मांगी गई है

संख्या क्रम	आवेदक के प्रश्न	उत्तर
i.	कोरोना वैक्सीन लेना स्वैच्छिक है या अनिवार्य, जबरदस्ती	कोरोना वैक्सीन लेना स्वैच्छिक है।
ii	क्या वैक्सीन नहीं लेने पर सारी सरकारी सुविधाएं बंद कर दी जायगी, सरकारी योजना पेंशन	आवेदन मे लिखी बातें निराधार है। किसी भी सरकारी सुविधा, नागरिकता, नौकरी इत्यादि से वैक्सीन का कोई सम्बन्ध नही है।
iii	क्या वैक्सीन नहीं लेने पर नौकरी नहीं मिलेगा, ट्रेन, बस, मेट्रो मे चढने नहीं मिलेगी	
iv	यदि कोई ias ips स्वास्थ्य या पुलिस कर्मचारी नागरिक को धमकी दे की वैक्सीन ले नही तो ये कर देगे तो नागरिक क्या कर सकती क्या कोर्ट जा सकते है	
v	क्या वैक्सीन नहीं लेने पर स्कूलों, कॉलेज, विश्वविद्यालय, गैस कनेक्शन, पानी, बिजली कनेक्शन, राशन आदि के लिए क्या वैक्सीन नहीं मिलेगे	
vi	क्या वैक्सीन नही लेने पर नौकरी से निकला जा सकता है वेतन रोका जा सकत है, निजी और सरकारी विभाग दोनों मे।	

d/c

सत्यमेव जयते

NATIONAL DISASTER MANAGEMENT PLAN

November 2019

NATIONAL DISASTER MANAGEMENT AUTHORITY
MINISTRY OF HOME AFFAIRS
GOVERNMENT OF INDIA

State Disaster Managment Authority (SDMA)

As per provisions in Chapter-III of the DM Act, each State Government shall establish a State Disaster Management Authority (SDMA) or its equivalent as notified by the state government with the Chief Minister as the Chairperson. In case of other UTs, the Lieutenant Governor or the Administrator shall be the Chairperson of that Authority. For the UT of Delhi, the Lieutenant Governor and the Chief Minister shall be the Chairperson and Vice-Chairperson respectively of the State Authority. In the case of a UT having Legislative Assembly, except the UT of Delhi, the Chief Minister shall be the Chairperson of the Authority established under this section. The SDMA will lay down policies and plans for DM in the State. The SDMA will approve the disaster management plans prepared by various departments. It will, inter alia approve the State Plan in accordance with the guidelines laid down by the NDMA, coordinate the implementation of the State Plan, recommend provision of funds for mitigation and preparedness measures and review the developmental plans of the different departments of the State to ensure the integration of prevention, preparedness and mitigation measures. The State Government shall constitute a State Executive Committee (SEC) to assist the SDMA in the pe rformance of its functions. The SEC will be headed by the Chief Secretary to the State Government. The SEC will coordinate and monitor the implementation of the National Policy, the National Plan, and the State Plan. The SEC will also provide information to the NDMA relating to different aspects of DM.

1.15. Plan Implementation

The Act mandates that every Ministry and Department of the Government of India and every state must prepare a DMP in accordance with the NDMP. Respective DM authorities must regularly review and update their DM plans. Central ministries and state governments will integrate DRR into their development policy, planning and programming at all levels. They must adopt a holistic approach and build multi-stakeholder partnerships at all levels, as appropriate, for the implementation of the DM plans. Depending on its nature, different components of the NDMP will be implemented within short, medium and long-term timeframes ending in 2030, with the actions under these timeframes often running concurrently and not sequentially. In a broad sense, the approach described in the NDMP applies to all those working for disaster risk reduction in the country, be it government, private, not-for-profit entities, national agencies or international organisations.

Writ Petition (Civil) No. 546 of 2020

Centre for Public Interest Litigation v. Union of India

2020 SCC OnLine SC 652

In the Supreme Court of India
(BEFORE ASHOK BHUSHAN, R. SUBHASH REDDY AND M.R. SHAH, JJ.)

Centre for Public Interest Litigation ... Petitioner(s);

Versus

Union of India ... Respondent(s).

Writ Petition (Civil) No. 546 of 2020
Decided on August 18, 2020

The Judgment of the Court was delivered by

ASHOK BHUSHAN, J.:— From the beginning of this year, 2020, the world including our country is in the grip of a pandemic known as Novel Coronavirus (COVID-19). On 31.12.2019, a cluster of cases of pneumonia of unknown cause in the city of Wuhan, Hubei Province in China was reported to the World Health Organisation (WHO). This was subsequently identified as a new virus in January, 2020 and over the following months, the number of cases continued to rise but were not contained to China and showed exponential growth worldwide. Due to the global rise in cases, this was declared a pandemic on 11.03.2020 by the WHO. The number of affected persons is increasing worldwide. Although, substantial population is also recovering from it but India witnessed exponential growth in number of cases in the last month.

2. The world is familiar with several kinds of disasters from time immemorial. Every country has faced one or other disaster in recent memory. Disasters disturb lives, societies and livelihood around the world. The impact of disaster is to strike hard earned economy, development and material gains. Many of the destructive hazards are natural in origin and some man made also. The whole world having faced adverse effect of different kinds of disasters is now well aware of its ill effect and steps internationally as well as nationally are being taken for last several decades to combat different kinds of disasters. U.N. General Assembly recognizing the importance of reducing the impact of natural disaster for all people including developing countries designated 1990 as the international decade of natural disaster reduction. The International Strategy for Disaster Reduction (UNISDR) was established following IDNDR of the 1990s. The UN/GA convened the second World Conference on Disaster Risk Reduction (DRR) in Kobe, Hyogo, Japan 2005, which concluded the review of the Yokohama Strategy and its Plan of Action and the adoption of the Hyogo Framework for Action 2005-2015 : Building the Resilience of Nations and Communities to Disasters (HFA) (UNISDR 2005) by 168 countries. The HFA outlined five priorities for action:

"(1) Ensure that DRR is a national and a local priority with a strong institutional basis for implementation;

(2) Identify, assess, and monitor disaster risks and enhance early warning;

(3) Use knowledge, innovation, and education to build a culture of safety and resilience at all levels;

(4) Reduce the underlying risk factors;

(5) Strengthen disaster preparedness for effective response at all levels."

3. On 23.12.2005, both the Houses of Indian Parliament passed a Disaster Management Bill. The Introduction and the Statement of Objects and Reasons of the Bill mentions:—

"INTRODUCTION

For prevention and mitigation effects of disasters and for undertaking a holistic, coordinated and prompt response to any disaster situation it has been decided by the Government to enact a law on disaster management to provide for requisite institutional mechanisms for drawing up and monitoring the implementation of the disaster management plans, ensuring measures by various wings of Government. To achieve this objective the Disaster Management Bill was introduced in the Parliament.

STATEMENT OF OBJECTS AND REASONS

The Government have decided to enact a law on disaster management to provide for requisite institutional mechanisms for drawing up and monitoring the implementation of the disaster management plans, 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."

4. The Disaster Management Act, 2005 (hereinafter referred to as "Act, 2005") was enacted to provide for the effective management of disasters and matters connected therewith or incidental thereto. The enactment of Disaster Management Act, 2005 was to bring in place requisite institutional mechanisms for drawing up and monitoring the implementation of the Disaster Management Plans and other measures by various wings of the Government for preventing and mitigating effects of disasters. We shall notice the

relevant provisions of the Act a little later.

5. In accord with Disaster Management Act, 2005, Union Cabinet approved a "National Policy on Disaster Management, 2009". Paragraph 1.1.1, 1.2.1 and 1.3.1 of the policy reads as under:—

> "1.1.1 Disasters disrupt progress and destroy the hard-earned fruits of painstaking developmental efforts, often pushing nations, in quest for progress, back by several decades. Thus, efficient management of disasters, rather than mere response to their occurrence, has in recent times, received increased attention both within India and abroad. This is as much a result of the recognition of the increasing frequency and intensity of disasters, as it is an acknowledgement that good governance in a caring and civilised society, needs to deal effectively with the devastating impact of disasters.
>
> 1.2.1 India is vulnerable, in varying degrees, to a large number of natural as well as man-made disasters. 58.6 per cent of the landmass is prone to earthquakes of moderate to very high intensity; over 40 million hectares (12 per cent of land) is prone to floods and river erosion; of the 7,516 km long coastline, close to 5,700 km is prone to cyclones and tsunamis; 68 per cent of the cultivable area is vulnerable to drought and hilly areas are at risk from landslides and avalanches. Vulnerability to disasters/emergencies of Chemical, Biological, Radiological and Nuclear (CBRN) origin also exists. Heightened vulnerabilities to disaster risks can be related to expanding population, urbanisation and industrialisation, development within high-risk zones, environmental degradation and climate change (Maps 1-4).
>
> 1.3.1 On 23 December 2005, the Government of India (GoI) took a defining step by enacting the Disaster Management Act, 2005, (hereinafter referred to as the Act) which envisaged the creation of the National Disaster Management Authority (NDMA), headed by the Prime Minister, State Disaster Management Authorities (SDMAs) headed by the Chief Ministers, and District Disaster Management Authorities (DDMAs) headed by the District Collector or District Magistrate or Deputy Commissioner as the case may be, to spearhead and adopt a holistic and integrated approach to DM. There will be a paradigm shift, from the erstwhile relief-centric response to a proactive prevention, mitigation and preparedness-driven approach for conserving developmental gains and to minimise loss of life, livelihood and property."

6. The policy noticed institutional framework under the Act, dealt with financial arrangement, disaster prevention, mitigation and preparedness.

7. Third U.N. World Conference on Disaster Risk Reduction was held in March, 2015 at Sendai, Japan. One of the declarations made in the conference was:—

> "We, the Heads of State and Government, ministers and delegates participating in the Third United Nations World Conference on Disaster Risk Reduction, have gathered from 14 to 18 March 2015 in Sendai City of Miyagi Prefecture in Japan, which has demonstrated a vibrant recovery from the Great East Japan Earthquake in March 2011. Recognizing the increasing impact of disasters and their complexity in many parts of the world, we declare our determination to enhance our efforts to strengthen disaster risk reduction to reduce disaster losses of lives and assets from disasters worldwide."

8. The Sendai declaration dealing with priorities for action emphasized following in paragraph 33(a):—

> "33(a) To prepare or review and periodically update disaster preparedness and contingency policies, plans and programmes with the involvement of the relevant institutions, considering climate change scenarios and their impact on disaster risk, and facilitating, as appropriate, the participation of all sectors and relevant stakeholders;"

9. Although Section 11 of Act, 2005 contemplated preparation of a National Plan, however, the National Plan was not prepared till the year 2016 as was noticed by this Court in a judgment of this Court in *Swaraj Abhiyan* v. *Union of India*, (2016) 7 SCC 498. In the year 2016, National Disaster Management Plan was prepared as required by Section 11 of the Act, 2005. The preparation of the National Plan under Section 11 was noticed by this Court in *Gaurav Kumar Bansal* v. *Union of India*, (2017) 6 SCC 730. In the same judgment, this Court noticed that State Plan under Section 23 of the Act (except by two States) and District Plan have also been prepared. The preparation of National Plan, State Plan and District Plan were noticed in paragraphs 7, 11 and 12 of the above judgment, which are to the following effect:—

> "7. It was further pointed out that a National Plan has been approved and placed on the website of the NDMA in terms of Section 11 of the Act and the guidelines for minimum standards of relief Under Section 12 of the Act have also been placed on the website of the NDMA.
>
> 11. As far as the preparation of the State Plan Under Section 23 of the Act is concerned, we have been informed by the learned Counsel for NDMA that all States except Andhra Pradesh and Telangana have prepared a State Disaster Management Plan which is very much in place.
>
> 12. As far as the districts are concerned, it is stated that the District Disaster Management Authority has been constituted in every district Under Section 25 of the Act and out of 684 districts in the country, a District Disaster Management Plan is in place in 615 districts while it is under process in the remaining districts."

10. The revision of the existing National Disaster Management Plan, 2016 began in April, 2017 and completed in November, 2019. The National Disaster Management Plan approved by National Disaster

Management Authority was notified in November, 2019.

11. This writ petition filed as a public interest litigation has been filed in the wake of Covid-19 pandemic, seeking direction to the Union of India to prepare, notify and implement a National Plan under Section 11 read with Section 10 of the Act, 2005 to deal with current pandemic (Covid-19) and to lay down minimum standards of relief under Section 12 of the Act, 2005 to be provided to persons affected with COVID-19. Petitioners have also sought for directions to utilize National Disaster Response Fund (NDRF) for the purposes of providing assistance in the fight against COVID-19 and all the contributions/grants from individuals/institutions be credited in NDRF and not to PM CARES Fund and all funds collected in PM CARES Fund till date should be directed to be transferred to NDRF. It is useful to note the specific prayers (a) to (c) made in the writ petition:—

"a. Issue a writ, order or direction to the Union of India to prepare, notify and implement a National Plan under Section 11 read with Section 10 of the Disaster Management Act, 2005 to deal with the ongoing COVID-19 pandemic;

b. Issue a writ, order or direction to the Union of India to lay down minimum standards of relief, under Section 12 of the Disaster Management Act, 2005, to be provided to persons affected by the COVID-19 virus, as well as by the resultant national lockdown;

c. Issue a writ, order or direction to the Union of India to utilize NDRF for the purpose of providing assistance in the fight against GOVID-19 pandemic in compliance with Section 46 of the DM Act, all the contributions/grants from individuals and institutions shall be credited to the NDRF in terms of Section 46(1)(b) rather than to PM CARES Fund and all the fund collected in the PM CARES Fund till date may be directed to be transferred to the NDRF;"

12. We have heard Shri Dushyant Dave, learned senior counsel for the petitioner. Shri Kapil Sibal has also made his submissions in support of the prayers and issues raised in the writ petition while addressing his submissions in Suo Moto Writ Petition No. 6 of 2020. We have also heard Shri Tushar Mehta, learned Solicitor General appearing for the Union of India.

13. Petitioner's case in the writ petition is that the National Plan uploaded on the website of National Disaster Management Authority of the year 2019 does not deal with situations arising out of the current pandemic and has no mention of measures like lockdown, containment zones, social distancing etc. The Central Government has notified COVID-19 as a "disaster" under Act, 2005 and has issued series of notifications to contain the instant pandemic. Petitioner pleads that Centre need to prepare a well-drawn National Plan to deal with instant pandemic and the same need to be prepared after due consultation with the State Government and experts. Petitioner further pleads that Centre should come up with detailed guidelines recommending the minimum standards of relief to be provided in the relief camps in relation to shelter, food, drinking water, medical cover and sanitation, in absence of which, shelter homes and relief camps are susceptible of becoming hotbeds for the spread of COVID-19 infection. Petitioner pleads that Centre should come up with detailed guidelines under Section 12(ii) and (iii) of the Act, 2005 recommending special provisions to be made for widows and orphans and ex gratia to be provided to the kith and kin of those losing life not just because of COVID-19 infection but also due to harsh lockdown restrictions.

14. The petitioner's case further is that the grants/contributions by individuals and institutions should be credited into the National Disaster Response Fund (NDRF) under Section 46 of the Act, 2005 and NDRF should be utilized for meeting the ongoing COVID-19 crisis. All the contributions made by the individuals and institutions in relation to COVID-19 are being credited into the PM CARES Fund and not in NDRF, which is clear violation of Section 46 of the Act, 2005. The NDRF is subject to CAG Audit and PM CARES Fund is not subject to CAG Audit. Petitioner's case further is that the Centre may be directed to utilize NDRF for the purpose of drawing assistance to fight against COVID-19 and all the contributions/grants from individuals and institutions be credited to the NDRF in terms of Section 46(1)(b) rather than to PM CARES Fund and all the Fund Collected in the PM CARES Fund till date may be directed to be transferred to the NDRF.

15. A preliminary counter affidavit has been filed on behalf of the Union of India. In the counter affidavit, the respondents have questioned the locus of the petitioner to file this public interest litigation. Counter affidavit questions as to whether there can be a permanent body set up only to file litigation on issues, which the said body subjectively considers to be of "public interest". Counter affidavit pleads that National Disaster Management Plan as per Section 11 is already in place and relevant portion of National Disaster Management Plan - November, 2019 has been annexed as Annexure R-1 to the counter affidavit. Counter affidavit pleads that Act, 2005 provides for a broad framework in terms of the response to be provided in pursuance to a National Plan in case of any disaster. Counter affidavit pleads that National Plan does not and cannot contain step by step instructions or specific instructions for the day to day management by Government agencies in the situation of any particular and unforeseen disaster. National Plan is not a document that contains the microscopic details as to the day to day management of the issues arising out of different disasters. National Disaster Management Authority has issued various orders from time to time to take effective measures found required at the relevant point of time to contain the spread of COVID-19 in the country. The Chairperson of National Executive Committee has issued several guidelines from time to

time. National Disaster Management Authority has, in order to create preparedness with regard to any contingent biological disaster, has framed the "National Disaster Management Guidelines Management of Biological Disasters". National Disaster Management Authority has framed broad template for State level and District level for contingency plan for COVID-19. The Nodal Ministry, i.e., Ministry of Health and Family Welfare has issued a "Cluster Containment Plan for COVID-19" on 02.03.2020, which was further updated on 16.05.2020. Further instructions have been issued from time to time including the guidance documents. The Ministry of Health and Family Welfare has approved the India COVID-19 Emergency Response and Health Systems Preparedness Package of Rs. 15000 crores, which seeks to support States/Union Territories in various aspects of management of the COVID Pandemic and provides support for establishment of COVID dedicated facilities for treatment of COVID-19 cases including for critical care, enhancement in testing capacities, engagement and training of necessary human resources and procurement of essential equipment and protective gear for the health care personnel engaged in COVID-19 duties etc. With regard to minimum standards of relief, the counter affidavit refers and relies on guidelines on Minimum Standards of Relief under Section 12, which has been brought on record as Annexure R-7. The Counter affidavit also outlines various steps taken by Health Ministry as well as the Government of India.

16. Replying the averments in the writ petition regarding PM CARES Fund and NDRF, the counter affidavit pleads that there are several funds which are either established earlier or now for carrying out various relief works. PM CARES Fund is one of such funds with voluntary donations. Affidavit further states that there exist a NDRF which would not prohibit creation of a different fund like PM CARES fund which provides for voluntary donations. The directions prayed in the writ petition for transfer of funds received in PM CARES Fund in the NDRF are non-maintainable.

17. Shri Dushyant Dave, learned senior counsel appearing for the petitioner referring to the pleadings of the petitioner made in the writ petition contends that Centre was obliged to prepare a National Plan for Disaster Management specifically for COVID-19. Shri Dave does not dispute that National Plan under Section 11 has been framed in November, 2019 but he submits that said Plan is neither comprehensive nor covers management of pandemic, i.e., COVID-19. Shri Dave submits that power given in a Statute is to be exercised in the same manner. Shri Dave further submits that there is a serious problem in implementing the National Plan, 2019. Shri Dave has taken us to certain portion of Plan of November, 2019, which has been filed as Annexure - P-2 to the writ petition. Shri Dave submits that only paragraph 7.15 deals with biological and public health emergencies but Plan does not contemplate giving any financial relief. Shri Dave submits that unless there is a National Plan for COVID-19, effective measures cannot be taken to contain COVID-19. Referring to Section 46 of the Act, 2005, Shri Dave submits that NDRF having been constituted by Central Government, all amount given by individuals and organisations for disaster should have been credited in NDRF. He submits that PM CARES Fund should not have been constituted when NDRF is already in place to take care of disasters. Shri Dave submits that there is no provision in 2019 Plan to give fund to NDRF. Referring to Operational Guidelines for Constitution and Administration of the National Disaster Response Fund at page 129 of the writ petition, Shri Dave submits that paragraph 5.5 provides that contribution made by the persons or institutions for the purpose of disaster management to be credited in the NDRF, which clause 5.5 has been omitted in the subsequent Operational Guidelines for Constitution and Administration of the National Disaster Response Fund filed at page 154, which is recent guidelines. By deletion of clause 5.5 now contribution by any person or institution for the purpose of disaster management to the NDRF is not permissible. Shri Dave submits that petitioners have no reason to doubt the bonafide of PM CARES Fund but by creating PM CARES Fund the NDRF is being circumvented. What cannot be done directly cannot be done indirectly. Although, NDRF is audited by CAG, the PM CARES Fund is audited by only private auditors.

18. Shri Tushar Mehta, learned Solicitor General refuting the submissions of the counsel for the petitioners submits that reliefs (i) and (ii) made in the writ petition has become infructuous since National Plan has already been prepared under Section 11, which has been referred to in the counter affidavit and relevant extract of the Plan has already been brought on record as Annexure R-1 along with counter affidavit. He submits that insofar as the guidelines for minimum standards of reliefs are concerned, there are guidelines in existence, which has been brought on record by the counter affidavit, which covers all disasters including COVID-19. Shri Mehta submits that Plan - November, 2019 along with the powers given in the Act, 2005 contains several measures to contain the spread of COVID-19 and no separate National Plan is required for COVID-19.

19. Shri Tushar Mehta submits that a National Disaster Response Fund has been created as stipulated under Section 46 of Act, 2005, which consist of fund in the form of budgetary provisions made by the Central Government in National Disaster Response Fund. He submits that the existence of National Disaster Response Fund, which is a statutory fund, neither prevents creation of any public charitable trust receiving voluntary donation nor can remotely mean that the amount received in all such voluntary funds should go in the statutory fund created under Section 46. National Disaster Response Fund and PM CARES Fund being distinct and separate, there is no occasion for any direction to transfer the amount of PM CARES Fund to the National Disaster Response Fund.

20. We have heard the learned counsel for the parties and perused the record. Applications for

intervention are rejected.

21. The respondent in its affidavit has raised contention/objection regarding the locus standi of the petitioner. It is, inter alia, contended that there cannot be a permanent body existing only for filing public interest litigations. Shri Tushar Mehta, learned Solicitor General, however, pointed out that at the outset, in the facts of the present case, he would rather like to assist the Hon'ble court on merits and requested that the question of locus standi of the petitioner which, according to him is a very serious question, be left open to be raised and decided in other proceedings. We have, therefore, heard the parties on merits, keeping the aforesaid question open, to be heard and decided in an appropriate proceeding.

22. From the submissions of the learned counsel for the parties and the pleadings on record, following questions arise for consideration in this writ petition:—

I) Whether the Union of India under Section 11 of Act, 2005, is obliged to prepare, notify and implement a National Disaster Management Plan specifically for pandemic COVID-19 irrespective of National Disaster Management Plan notified in November, 2019?

II) Whether the Union of India is obliged to lay down the minimum standards of relief under Section 12 of Act, 2005, for COVID-19 irrespective of earlier guidelines issued under Section 12 of the Act, 2005 laying down the minimum standards of relief?

III) Whether Union of India is obliged to utilise National Disaster Response Fund created under Section 46 of the Act for the purpose of providing assistance in the fight of COVID-19?

IV) Whether all the contributions/grants from individuals and institutions should be credited to the NDRF in terms of Section 46(1) (b) of the Act rather than to PM CARES Fund?

V) Whether all the funds collected in the PM CARES Fund till date be directed to be transferred to the NDRF?

QUESTION NO. I

I) Whether the Union of India under Section 11 of Act, 2005, is obliged to prepare, notify and implement a National Disaster Management Plan specifically for pandemic COVID-19 irrespective of National Disaster Management Plan notified in November, 2019?

23. The Act, 2005, has been enacted for the effective management of Disasters and for matters connected therewith or incidental thereto. Section 3 of the Act constitutes National Disaster Management Authority with the Prime Minister of India as the Chairperson, ex-officio. Section 6 enumerates the powers and functions of National Authority. As per Section 6 sub-Section (2)(b), National Disaster Management Authority (hereinafter referred to as National Authority) is to approve the National Plan. Under Section 7, the National Authority may constitute an advisory Committee consisting of experts in the field of Disaster Management to make recommendations on different aspects of Disaster Management. Under Section 8, the Central Government is to constitute a National Executive Committee to assist the National Authority in the performance of its functions under the Act. Section 11 of the Act deals with National Plan, which provision is to the following effect:—

"11. National Plan -(1) There shall be drawn up a plan for disaster management for the whole of the country to be called the National Plan.

(2) The National Plan shall be prepared by the National Executive Committee having regard to the National Policy and in consultation with the State Governments and expert bodies or organizations in the field of disaster management to be approved by the National Authority.

(3) The National Plan shall include—

(a) measures to be taken for the prevention of disasters, or the mitigation of their effects;

(b) measures to be taken for the integration of mitigation measures in the development plans;

(c) measures to be taken for preparedness and capacity building to effectively respond to any threatening disaster situations or disaster;

(d) roles and responsibilities of different Ministries or Departments of the Government of India in respect of measures specified in clauses (a), (b) and (c).

(4) The National Plan shall be reviewed and updated annually.

(5) Appropriate provisions shall be made by the Central Government for financing the measures to be carried out under the National Plan.

(6) Copies of the National Plan referred to in sub-sections (2) and (4) shall be made available to the Ministries or Departments of the Government of India and such Ministries or Departments shall draw up their own plans in accordance with National Plan."

24. As noted above, the first National Plan under Section 11 was framed in the year 2016, which was revised and the National Plan was prepared and notified in November, 2019. Extract of National Disaster Management Plan of November, 2019 has been brought on record both by the petitioner as Annexure-P2 to the writ petition as well as by the respondent as Annexure-R1 to the preliminary counter affidavit.

25. We may notice certain relevant portions of the Plan, 2019 to answer the question which is up for consideration. The Plan, 2019 under heading 'Executive Summary' states:—

"...The National Disaster Management Plan (NDMP) provides a framework and direction to the government agencies for all phases of disaster management cycle. The NDMP is a "dynamic document" in the sense that it will be periodically improved keeping up with the emerging global best practices and knowledge base in disaster management. It is in accordance with the provisions of the DM Act, 2005, the guidance given in the National Policy on Disaster Management (NPDM) 2009, and the established national practices..."

26. In the Executive summary itself, while noticing the changes introduced, the Plan states that new sections have been added relating to several hazards including "Biological and Public Health Emergencies". The Plan, 2019 provides a framework and directions to the Government Agencies for all phases of Disaster Management. The Plan is a dynamic document in the sense that it was to be periodically improved, keeping up with the best practices and knowledge based in Disaster Management. The Plan provides a framework covering all aspects of Disaster Management. It covers Disaster Risk Reduction, mitigation, preparedness, response, recovery and building back better. It recognizes that effective Disaster Management necessitates a comprehensive framework encompassing multiple hazards. Paragraph 1.4 of the Plan under the heading 'Legal Mandate' statesx:—

"1.4. Legal Mandate

Section 11 of the DM Act 2005 mandates that there shall be a National Disaster Management Plan (NDMP) for the whole of India. The NDMP complies with the National Policy on Disaster Management (NPDM) of 2009 and conforms to the provisions of the DM Act making it mandatory for the various central ministries and departments to have adequate DM plans. While the NDMP will pertain to the disaster management for the whole of the country, the hazard-specific nodal ministries and departments notified by the Government of India will prepare detailed DM plans specific to the disaster assigned.

As per Section 37 of the DM Act, every ministry and department of the Government of India, be it hazard-specific nodal ministries or not, shall prepare comprehensive DM plans detailing how each of them will contribute to the national efforts in the domains of disaster prevention, preparedness, response, and recovery. As per the mandate of the DM Act, the NDMP assigns specific and general responsibilities to all ministries and departments for disaster management. The DM Act enjoins the NDMP to assign necessary responsibilities to various ministries to support and implement the plan. Therefore, it is incumbent on all ministries to accept all the implicit and explicit responsibilities mentioned in the NDMP even if they are beyond what are explicitly mentioned in the normal rules of business. Disaster management requires assumption of responsibilities beyond the normal functioning. The NDMP will be complemented by separate contingency plans, SOPs, manuals, and guidelines at all levels of the multi-tiered governance system."

27. The above part of the Plan categorically states that the Plan will be complemented by several contingency plans, Standard Operating Procedures (SOPs), Manuals and Guidelines at all levels of the multi-tiered governance system. Paragraph 1.13 deals with 'types of Disasters'. Paragraph 1.13.1, 'Natural Hazards' have been enumerated in five major categories. Sub-category (5) is to the following effect:—

"1.13.1 Natural Hazards

1)...

5) Biological Process or phenomenon or organic origin or conveyed by biological vectors, including exposure to pathogenic micro-organisms, toxins and bioactive substances that may cause loss of life, injury, illness or other health impacts, property damage, loss of livelihoods and services, social and economic disruption or environmental damage."

28. Under Table 1-1, 'Categories of Natural Hazards' have been detailed. Item (5) of the Table 1-1 is to the following effect:—

"Table 1-1 : Categories of Natural Hazards

	Family	Main Event	Short Description/Secondary Disaster
1	Geophysical		
2	Hydrological		
3	Meteorological		
4	Climatological		
5	Biological	Exposure to germs and toxic substances	• Epidemics : Viral, bacterial parasitic, fungal, or prion infections • Insect infestatio ns • Animal stampedes

29. Table 1-3, provides for 'Nodal Ministry for Management/Mitigation of Different Disasters' with regard to Biological Emergencies, Nodal Ministry is notified as Ministry of Health and Family Welfare(MoHFW). Under paragraph 2.2.3.3, Biological and Public Health Emergencies have been dealt with. The First

paragraph of the above is as follows:—

> "...Disasters related to this subgroup are biological emergencies and epidemics, pest attacks, cattle epidemics and food poisoning. Biological emergency is one caused due to natural outbreaks of epidemics or intentional use of biological agents (viruses and microorganisms) or toxins through dissemination of such agents in ways to harm human population, food crops and livestock to cause outbreaks of diseases. This may happen through natural, accidental, or deliberate dispersal of such harmful agents into food, water, air, soil or into plants, crops, or livestock. Apart from the natural transnational movement of the pathogenic organisms, their potential use as weapons of biological warfare and bioterrorism has become far more important now than ever before. Along with nuclear and chemical agents, many biological agents are now considered as capable of causing large-scale mortality and morbidity..."

30. Paragraphs 6 and 7 deals with "Building Disaster Resilience - Responsibility Framework, Part A and B". Dealing with Biological and Public Health Emergencies in paragraph 7.15, following are the sub-heads under the paragraph:—

> "7.15 Biological and Public Health Emergencies (BPHE)
> 7.15.1 Understanding Risk
> 7.15.2 Inter-Agency Coordination
> 7.15.3 Investing in DRR-Structural Measures
> 7.15.4 Investing in DRR-Non-structural Measures
> 7.15.5 Capacity Development
> 7.15.6 Climate Change Risk Management"

31. A detailed chart has been prepared under paragraph 7.15 in five parts and it shall be useful to notice the only first portion of paragraph 7.15.1, item 1, which is to the following effect:—

> "7.15.1 Understanding Risk

Biological & Public Health Emergencies (BPHE)					
	Sub-Thematic Area for DRR	Central/State Agencies and their Responsibilities			
		Centre#	Responsibility - Centre	State#	Responsibility-State
1.	Observation Networks, Information Systems, Monitoring, Research, Forecasting, Early Warning and Zoning/Mapping	MHFW*(NCDC), MAFW, MHA, MOD, MOES, MOEFCC, MOR, MLBE, MEITY, NDMA	<u>Recurring/Regular (RR)</u> • Support for training • Extend technical support <u>Medium Term(T2)</u> • Establishment of Early Warning System • Strengthening IDSP and early warning systems at regional levels • Epidemiological disease mapping • Health facilities mapping	HFWD*, DMD$, SDMA, RD, DRD, UDD, DWSD, EDD, PD, EFD, AHD, WCD, PRI/ULB, SLRTI, DDMA	<u>Recurring/Regular (RR)</u> Maintaining preventive measures as per norms <u>Short Term(T1)</u> Strengthening integrated health surveillance systems <u>Medium Term(T2)</u> • Establishing and maintain community-based network for sharing alerts • Strengthening IDSP <u>Long Term(T3)</u> States should, modify or adapt IMD's warning system according to thresholds applicable in each state

32. The other items apart from item (1) as noticed above in paragraph 7, which are relevant is as follows:—

Biological & Public Health Emergencies (BPHE)					
	Sub-Thematic Area for DRR	Central/State Agencies and their Responsibilities			
		Centre#	Responsibility - Centre	State#	Responsibility-State

2.	Hazard Risk Vulnerability and Capacity Assessment (HRVCA)	MHFW*, MAFW*, MHA, MOD, MOES, MOEFCC, MSJE, NDMA	Recurring/Regular (RR) • Promote studies, documentation and research • Provide Training & Technical support • Studies on vulnerabilities and capacities covering social, physical, economic, ecological, gender, social inclusion and equity aspects Short-Term (T1) Develop guidelines	HFWD, DMD$, SDMA, DRD, UDD, DWSD, EFD, AHD, WCD, DSJE, PRI, ULB, SLRTI, DDMA	Recurring/Regular(RR) • Updating HRVCA • Identifying the vulnerable population/communities/settlements • Identification of groups requiring special attention • Conduct audit of equipment and hu man resource requirements Short term(T1) Constitute/strengthen the mechanisms for consultation with experts and stakeholders
3	Dissemination of warnings, data & information	MHFW, MHA, MOD, MOES, MAFW, MOEFCC, NDMA	Recurring/Regular (RR) • Support for organising training • Extend technical support	HFWD*, DMD$, SDMA, DRD, UDD, DWSD, EDD, PD, EFD, AHD, WCD, PRI, ULB, SLRTI, DDMA	Short Term (T1) • Create awareness preventive measures • Extensive IEC campaigns to create awareness through print, electronic and social media Medium Term (T2) Specific messages for highly vulnerable groups such as elderly, young children, outdoor workers and slum residents
4	Disaster Data Collection and Management	MHA*, MOSPI, all ministries/depts.	Recurring/Regular (RR) Systematic data management of data on disaster damage and loss assessments Short Term (T1) Disaster Damage and Losses 2005-2015 baseline	DMD$, SDMA, all depts.	Recurring/Regular (RR) Systematic data management of data on disaster damage and loss assessments Short Term (T1) Disaster Damage and Losses 2005-2015 baseline

Notes : (#) Every ministry, department or agency of the government - central and state - not specifically mentioned will also have both direct and indirect supporting role depending on the disaster, location and context. (*) The ministry, department or agency with this symbol has or is deemed to have a nodal or lead role, while others mentioned have a direct or explicit supporting role. ($) DMD —Disaster Management Department : The state government department acting as the nodal department for disaster management, which is not the same in every state/UT.

33. Paragraph 7.15.2 deals with inter-agency coordination in these items. Paragraph 7.15.3 deals with investing in DRR - Structural measures. Paragraph 7.15.4 deals with investing in DRR - Non-structural measures. Paragraph 7.15.5 deals with capacity development. Paragraph 7.15.6 deals with climate change risk management. The plan, thus, contains detailed treatment of Biological and Public Health Emergencies as noticed above, which have been detailed at pages 117 to 130 of the Annexure-R1 of the counter affidavit. All aspects of Biological and Public Health Emergencies have been, thus, dealt in systematic and planned manner. The Plan of 2019 in different paragraphs deals with entire framework.

34. The submission which has been pressed by petitioner is that despite existence of Plan, 2019, there has to be specific Plan dealing with COVID-19, hence, Union of India may be directed to prepare a National Plan under Section 11 for COVID-19. Section 11 of the Act provides that there shall be a plan for Disaster Management for the whole of the Country. Sub-Section (3) of Section 11 requires that the National Plan shall include:—

"11.(3) The National Plan shall include—

(a) measures to be taken for the prevention of disasters, or the mitigation of their effects;

(b) measures to be taken for the integration of mitigation measures in the development plans;

(c) measures to be taken for preparedness and capacity building to effectively respond to any threatening disaster situations or disaster;

(d) roles and responsibilities of different Ministries or Departments of the Government of India in respect of measures specified in clauses (a), (b) and (c)."

35. The object and purpose of preparing a National Plan is to cope up and tackle with all conceivable disasters which the country may face. When the measures have to be taken for preparedness and capacity building to effectively respond to any threatening disaster situation, the section does not contemplate preparation of Plan after a disaster has occurred.

36. National Plan and guidelines as contemplated by the statute for Disaster Management is by its very nature prior to the occurrence of any disaster and as a measure of preparedness. It is not conceivable that a National Plan would be framed after the disaster has occurred. A National Plan encompasses and contemplate all kinds of disasters.

37. As noticed above, Biological and Public Health Emergencies has already been contemplated in the National Plan, 2019, which as noticed in table 1-1 under paragraph 1.13.1 specifically includes epidemics: Viral, Bacterial, Parasitic, Fungal and prion infections. Novel Coronavirus is an epidemic which has become a pandemic. Epidemics of different nature and extent have taken place in this country as well as other countries of the world. A pandemic is an epidemic, i.e., spread over multiple countries/continents. An epidemic, as a disaster has been known and recognized throughout the world with which most of the countries are infected time and again. As noticed above, Plan-2019 is complemented by several plans, Standard Operating Procedures (SOPs), Manuals, Guidelines at all levels of the Government.

38. The National Disaster Management Authority, Government of India, had issued National Disaster Management Guidelines in July, 2008 on subject "Management of Biological Disasters". The guideline specifically notices that "Biological Disasters" might be caused by epidemics, the guidelines states:—

"Biological disasters might be caused by epidemics, accidental release of virulent microorganism(s) or Bioterrorism (BT) with the use of biological agents such as anthrax, smallpox, etc. The existence of infectious diseases has been known among human communities and civilisations since the dawn of the history. The Classical literature of nearly all civilisations record the ability of major infections to decimate populations, thwart military campaigns and unsettle nations. Social upheavals caused by epidemics have contributed in shaping history over the ages..."

39. Thus, the National Disaster Management Authority was well aware of the epidemics and had issued guidelines in the year 2008 itself which has been further detailed in Plan-2019. All aspects of the epidemics, all measures to contain an epidemic, preparedness, response, mitigation have been elaborately dealt in Plan, 2019. Unless the National Plan as contemplated under Section 11 contains all aspects of disaster including the Biological and Public Health Emergencies, it will not be possible for the Governments to immediately respond and contain an epidemic.

40. The Disaster Management Act, 2005 contain ample powers and measures, which can be taken by the National Disaster Management Authority, National Executive Committee and Central Government to prepare further plans, guidelines and Standard Operating Procedure (SOPs), which in respect to COVID-19 have been done from time to time. Containment Plan for Novel Coronavirus, 2019 has been issued by Ministry of Health and Family Welfare, Government of India, copy of which updated up to 16.05.2020 has been brought on record as Annexure-R4. There are no lack of guidelines, SOPs and Plan to contain COVID-19, by Nodal Ministry and Annexure R-6 has been brought on record issued by Ministry of Health and Family Welfare, Government of India, i.e., Updated Containment Plan for Large Outbreaks Novel Coronavirus Disease, 2019 (COVID-19).

41. National Executive Committee as well as Nodal Ministry has issued guidelines and orders from time to time to regulate all measures to contain COVID-19. The petitioners are not right in their submissions that there is no sufficient plan to deal with COVID-19 pandemic. COVID-19 being a Biological and Public Health Emergency, which has been specifically covered by National Plan, 2019, which is supplemented by various plans, guidelines and measures, there is no lack or dearth of plans and procedures to deal with COVID-19.

42. We may also notice that this Court in *Gaurav Kumar Bansal* v. *Union of India*, (2017) 6 SCC 730, has noticed that National Plan under Section 11 has already been approved by National Disaster Management Authority. In paragraph 7 of the judgment, following was laid down:—

"7. It was further pointed out that a National plan has been approved and placed on the website of NDMA in terms of Section 11 of the Act and the guidelines for minimum standards of relief under Section 12 of the Act have also been placed on the website of NDMA."

43. In view of above discussion, we do not find any merit in the claim of the petitioner that Union of India be directed to prepare a National Plan under Section 11 for COVID-19. National Plan, 2019 have already been there in place supplemented by various orders and measures taken by competent authorities under Disaster Management Act, 2005, there is no occasion or need to issue any direction to Union of India to prepare a fresh National Plan for COVID-19. We, thus, hold that Union of India is not obliged to prepare,

notify and implement a fresh National Disaster Management Plan for COVID-19.

QUESTION NO. II

II) Whether the Union of India was obliged to lay down the minimum standards of relief under Section 12 of Act, 2005, for COVID-19 irrespective of earlier guidelines issued under Section 12 of the Act laying down the minimum standards of relief?

44. Section 12 of the Act, deals with guidelines for Minimum Standards of Relief. Section 12 is as follows:—

> "12. Guidelines for minimum standards of relief. — The National Authority shall recommend guidelines for the minimum standards of relief to be provided to persons affected by disaster, which shall include, —
>
> (i) the minimum requirements to be provided in the relief camps in relation to shelter, food, drinking water, medical cover and sanitation;
>
> (ii) the special provisions to be made for widows and orphans;
>
> (iii) ex gratia assistance on account of loss of life as also assistance on account of damage to houses and for restoration of means of livelihood;
>
> (iv) such other relief as may be necessary."

45. The petitioner's case as noticed above is that the Centre should come up with detailed guidelines under Section 12(ii) and (iii) of Disaster Management Act, 2005, recommending special provisions to be made for widows and orphans and ex-gratia assistance to be provided to the kith and kin of those losing life because of COVID-19 infections but also as a result of harsh lockdown restrictions. It is submitted that there are no guidelines providing for minimum standards for COVID-19. The above claim of the petitioner is refuted by the respondents. The respondents have brought on record the guidelines of minimum standards of relief under Section 12 as existing prior to COVID-19, which has been filed as Annexure-R7 to the counter affidavit. The guidelines filed as Annexure-R7 deals with

(i) definition of Relief and Rehabilitation Camp,

(ii) Minimum standards in respect of Shelter in relief camps,

(iii) Minimum Standards in respect of Food in relief camps,

(iv) Minimum Standards in respect of Water in relief camps,

(v) Minimum Standards in respect of Sanitation in relief camps,

(vi) Minimum Standards in respect of medical cover in relief camps and

(vii) Minimum Standards of Relief for Widows and Orphans.

46. The guidelines brought on record under Annexure-R7, which were in existence since before declaration of COVID-19 pandemic, covers all statutory requirement as enumerated in Section 12. Section 12 contemplates minimum standards of relief to be provided to persons affected by disaster. The word 'disaster' mentioned in Section 12 encompasses all the disasters including the present disaster. Section 12 does not contemplate that there shall be different guidelines for minimum standards of relief for different disasters.

47. The uniform guidelines are contemplated so that persons affected by disaster are provided with minimum requirement in the relief camps in respect of shelter, food, drinking water, medical cover and sanitation and other reliefs as contemplated in the section. There being already guidelines for minimum standards in place even before COVID-19, the said guidelines for minimum standards holds good even for those who are affected by COVID-19. Section 12 does not contemplate that afresh guidelines for the minimum standards of relief be issued with regard to COVID-19. The prayer of the petitioner to direct the Union of India to issue fresh guidelines under Section 12 to be provided to persons infected with COVID-19 is misconceived.

48. The Government of India vide order dated 14.03.2020 has decided to treat COVID-19, the pandemic, as a notified disaster for the purpose of providing assistance under State Disaster Response Fund, norms of assistance for ex-gratia payment to families of deceased persons, norms of assistance for COVID-19 positive persons requiring hospitalization and some other assistance to be provided from State Disaster Response Fund have been notified by the Government of India.

49. In view of the foregoing discussions, we hold that Union of India is not obliged to lay down minimum standards of relief under Section 12 of the Act, 2005 for COVID-19 and the guidelines issued under Section 12 providing for minimum standards of relief holds good for pandemic COVID-19 also.

QUESTION NOS. 3, 4 AND 5

III) Whether Union of India is obliged to utilise National Disaster Response Fund created under Section 46 of the Act for the purpose of providing assistance in the fight of COVID-19?

IV) Whether all the contributions/grants from individuals and institutions should be credited to the NDRF in terms of Section 46(1) (b) of the Act rather than PM CARES Fund?

V) Whether all the funds collected in the PM CARES Fund till date be directed to be transferred to the NDRF?

50. All the three questions being inter-related are taken together. The submissions of the petitioner centre around National Disaster Response Fund (NDRF) and PM CARES Fund. We need to notice the nature and character of these funds for appreciating the submissions made by the learned counsel for the parties. Chapter IX of the Disaster Management Act, 2005 deals with Finance, Accounts and Audit. Section 46 provides for National Disaster Response Fund. Section 46 reads:

> "46. National Disaster Response Fund.—(1) The Central Government may, by notification in the Official Gazette, constitute a fund to be called the National Disaster Response Fund for meeting any threatening disaster situation or disaster and there shall be credited thereto—
>
> (a) an amount which the Central Government may, after due appropriation made by Parliament by law in this behalf provide;
>
> (b) any grants that may be made by any person or institution for the purpose of disaster management.
>
> (2) The National Disaster Response Fund shall be made available to the National Executive Committee to be applied towards meeting the expenses for emergency response, relief and rehabilitation in accordance with the guidelines laid down by the Central Government in consultation with the National Authority."

51. The Central Government by notification dated 27.09.2010 which was published in Gazette Extraordinary on 28.09.2010 issued under sub-Section (1) of Section 46 of Act, 2005 constituted "National Disaster Response Fund". The notification dated 27.09.2010 reads:

> "MINISTRY OF HOME AFFAIRS
>
> NOTIFICATION
>
> New Delhi, the 27th September, 2010
>
> s.O.2346(E).- In exercise of the powers conferred by sub-section (1) of Section 46 of the Disaster Management Act, 2005 (53 of 2005), the Central Government hereby constitutes the National Disaster Response Fund (hereinafter NDRF) for meeting any threatening disaster situation or disaster.
>
> [F. No. 32-3/2010-NDM-I]
>
> R.K. SRIVASTAVA, Jr. Secy."

52. Ministry of Home Affairs (Disaster Management Division) has issued guidelines on Constitution and Administration of the National Disaster Response Fund (NDRF). Section 46(1) as noted above contemplates crediting of two kind of amounts, i.e., (a) an amount which the Central Government may, after due appropriation made by Parliament by law in this behalf provide; and (b) any grants that may be made by any person or institution for the purpose of disaster management.

53. The guidelines for constitution and administration of NDRF have been brought on record by the petitioner at page 129 of the writ petition. The guidelines came into force with effect from financial year 2010-11. Paragraph 3.1 enumerated the calamities covered under NDRF. Paragraph 3.1 is as follows:

> "3.1 Natural calamities of cyclone, drought, earthquake, fire, flood, tsunami, hailstorm, landslide, avalanche, cloud burst and pest attack considered to be of severe nature by Government of India and requiring expenditure by a State Government in excess of the balances available in its own State Disaster Response Fund (SDRF), will qualify for immediate relief assistance from NDRF."

54. Paragraph 5 of the guidelines deals with contribution to the NDRF. Paragraphs 5.1 to 5.5 are as follows:

> "5.1 The closing balance of the NCCF at the end of financial year 2009-10 shall be the opening balance of the NDRF in the year 2010-11.
>
> 5.2 Funds will be credited into the NDRF in accordance with the provisions of the Disaster Management Act, 2005.
>
> 5.3 The budget provision for transferring funds to the NDRF as mentioned in para 5.2 above shall be made in the Demand for grants no. 35- "Transfers to State and UT Governments" (under non-plan provision). Releases to State Governments will be made by the Ministry of Finance from this provision.
>
> 5.4 During the years 2010-15 transfers to the NDRF established in the Public Account of India will be made by operating the following heads of account : Major Head "2245-Relief on account of Natural Calamities - 80- General-797-Transfers to Reserve Funds and Deposit Account'-Transfer to National Disaster Response Fund.
>
> 5.5 Contributions made by any person or institution for the purpose of disaster management will also be credited to the NDRF. Modalities covering such contributions will be prescribed in due course."

55. Paragraph 7.1 of the guidelines deals with assessment of relief assistance from the NDRF. Paragraph 7.1 is as follows:

> "7.1 Upon a request made by a State not having adequate balance in its State Disaster Response Fund (SDRF), Ministry of Home Affairs or the Ministry of Agriculture, as the case may be, will assess whether a case for additional assistance from NDRF is made out under these guidelines and the approved items and norms of assistance under NDRF/SDRF. The following procedure will be adopted for making such assessment:

(i) The memorandum of the State Government will be examined to assess the likely requirement of funds as per items and norms of expenditure under SDRF/NDRF. If the preliminary examination reveals that there are adequate funds in SDRF with the State for providing relief as per norms, the State would be advised accordingly.

(ii) If the preliminary examination reveals that the State is in need of assistance, a Central Team will be deputed for making an on the spot assessment.

(iii) The report of the Central Team shall be examined by the National Executive Committee (NEC) constituted under section 8 of the DM Act, 2005. The NEC will assess the extent of assistance and expenditure which can be funded from the NDRF, as per the norms of NDRF/SDRF, and make recommendations.

(iv) Based on the recommendations of NEC, a High Level Committee (HLC) will approve the quantum of immediate relief to be released from NDRF."

56. The guidelines for administration of the NDRF have been revised with effect from financial year 2015-16 which have been brought on record at page 154 of the writ petition. Paragraph 3.1 of the guidelines is same as under guidelines for the financial year 2010-11. Paragraph 4.1 provides:

"4.1 The NDRF will be operated by the Government of India for the purpose of providing immediate relief to people affected by the above mentioned calamities which are assessed as being of 'severe nature', following the procedure described in para 7 of these guidelines. NDRF is classified in the Public Account in the sub-section (b) 'Reserve Funds not bearing Interest' of the Government of India under the major head 8235- 'General and other Reserve Funds' - 119- National Disaster Response Fund".

57. Paragraph 5 deals with contribution to the NDRF and there are some changes in the guidelines in paragraph 5. Paragraphs 5.1 to 5.4 of the new guidelines are as follows:

"5.1 The closing balance of the NDRF at the end of financial year 2014-15 shall be the opening balance of the NDRF in the year 2015-16.

5.2 Funds will be credited into the NDRF in accordance with the provisions of the section 46 (a) & (b) of Disaster Management Act, 2005.

5.3 The budget provision for transferring funds to the NDRF as mentioned in para 5.2 above shall be made in the Demand for grants no. 35- "Transfers to State and UT Governments" (under non-plan provision). Releases to State Governments will be made by the Ministry of Finance from this provision.

5.4 During the years 2015-20 transfers to the NDRF established in the Public Account of India will be made by operating the following heads of account : Major Head "2245-Relief on account of Natural Calamities - 80-General-797-Transfers to Reserve Funds and Deposit Account'-Transfer to National Disaster Response Fund."

58. The above is the scheme. As per paragraph 10 of the new guidelines, expenditure from NDRF is meant to assist a State to provide immediate relief in those cases of severe calamity, where the expenditure required is in excess of the balance in the State's SDRF. The NDRF is a statutory fund required to be audited by the Comptroller & Auditor General of India, which was constituted under Act, 2005 and is still in existence for the purposes as enumerated in the statute as well as in the guidelines issued under Act, 2005.

59. We may now notice the PM CARES Fund. Petitioner has brought on record certain details of PM CARES Fund as Annexure-P13. The details about the PM CARES Fund as brought on record as Annexure-P13 of the writ petition are as follows:

"Keeping in mind the need for having a dedicated national fund with the primary objective of dealing with any kind of emergency or distress situation, like posed by the COVID-19 pandemic, and to provide relief to the affected, a public charitable trust under the name of 'Prime Minister's Citizen Assistance and Relief in Emergency Situations Fund' (PM CARES Fund)' has been set up.

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Objectives:

- To undertake and support relief or assistance of any kind relating to a public health emergency or any other kind of emergency, calamity or distress, either man-made or natural, including the creation or upgradation of healthcare or pharmaceutical facilities, other necessary infrastructure, funding relevant research or any other type of support.
- To render financial assistance, provide grants of payments of money or take such other steps as may be deemed necessary by the Board of Trustees to the affected population.
- To undertake any other activity, which is not inconsistent with the above Objects.

Constitution of the Trust:

- Prime Minister is the ex-officio Chairman of the PM CARES Fund and Minister of Defence, Minister of Home Affairs and Minister of Finance, Government of India are ex-officio Trustees of the Fund.
- The Chairperson of the Board of Trustees (Prime Minister) shall have the power to nominate three trustees to the Board of Trustees who shall be eminent persons in the field of research, health, science, social work, law, public administration and philanthropy.

• Any person appointed a Trustee shall act in a pro bono capacity.

Other details:

• The fund consists entirely of voluntary contributions from individuals/organizations and does not get any budgetary support. The fund will be utilised in meeting the objectives as stated above.

• Donations to PM CARES Fund would qualify for 80G benefits for 100% exemption under the Income Tax Act, 1961. Donations to PM CARES Fund will also qualify to be counted as Corporate Social Responsibility (CSR) expenditure under the Companies Act, 2013

• PM CARES Fund has also got exemption under the FCRA and a separate account for receiving foreign donations has been opened. This enables PM CARES Fund to accept donations and contributions from individuals and organizations based in foreign countries. This is consistent with respect to Prime Minister's National Relief Fund (PMNRF). PMNRF has also received foreign contributions as a public trust since 2011.

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60. From the above details, it is clear that PM CARES Fund has been constituted as a public charitable trust. After outbreak of pandemic COVID-19, need of having a dedicated national fund with objective of dealing with any kind of emergency or distress situation, like posed by the COVID-19 pandemic, and to provide relief to the affected, a fund was created by constituting a trust with Prime Minister as an ex-officio Chairman of PM CARES Fund, with other ex-officio and nominated Trustees of the Fund. The PM CARES Fund consists entirely of voluntary contributions from individuals/organisations and does not get any Budgetary support. No Government money is credited in the PM CARES Fund.

61. After noticing constitution of NDRF as well as PM CARES Fund now we may notice the contentions raised by Shri Dave. The submission of Shri Dave is that the earlier guidelines for administration of NDRF which came into force with effect from financial year 2010-11 have been modified by new guidelines with effect from financial year 2015-16, and now it is not possible for any person or institution to make contribution to the NDRF. Shri Dave submits that paragraph 5.5 of earlier guidelines has been deleted to benefit the PM CARES Fund so that all contributions by any person or institution should go in the PM CARES Fund. Shri Dave submits that deletion of paragraph 5.5 of earlier guidelines (at page 130) in the new guidelines (at page 154-155) makes it clear that now it is not possible for any person or institution to make any contribution to NDRF.

62. There are two reasons for not accepting the above submission. Firstly, paragraph 5.5 of earlier guidelines which contemplated contributions by any person or institution for the purpose of disaster management to the NDRF are very much still there in the new guidelines, which have come into force with effect from financial year 2015-16. New guidelines contain the same heading, i.e., "Contribution to the NDRF" and guideline 5.2 provides "Funds will be credited into the NDRF in accordance with the provisions of the Section 46(1)(a) & (b) of the Disaster Management Act, 2005." The above guideline 5.2 specifically referred to Section 46(1)(a) & (b) and Section 46(1)(b) expressly provides that any grants that may be made by any person or institution for the purpose of disaster management shall be credited into the NDRF. The submission that after the new guidelines, it is not possible for any person or institution to make any contribution to the NDRF is, thus, misconceived and incorrect. According to the statutory provisions of Section 46 as well as new guidelines enforced with effect from financial year 2015-16 any person or institution can still make contribution to the NDRF.

63. Secondly, the PM CARES Fund has been constituted in the year 2020 after outbreak of pandemic COVID-19 whereas the new guidelines came into force with effect from 2015-16, on which date the PM CARES Fund was not in existence, hence, the submission that new guidelines were amended to benefit the PM CARES Fund is wholly misconceived.

64. Another limb of submission of Shri Dave is that although the Government of India vide its letter dated 14.03.2020 has decided to treat COVID-19 as a notified disaster for the purpose of providing assistance under SDRF but no similar notification has been issued for the purpose of providing assistance for COVID-19 under NDRF. The notification dated 14.03.2020 has been brought on record as Annexure-P10 of the writ petition which reads as follows:

"No. 33-4/2020-NDM-I
Government of India
Ministry of Home Affairs
(Disaster Management Division)

C-Wing, 3rd Floor, NDCC-II
Jai Singh Road, New Delhi -110001
Dated 14.03.2020

To

The Chief Secretaries (All States)

Subject : Items and Norms of assistance from the State Disaster Response Fund (SDRF) in wake of COVID-19 Virus Outbreak

Sir/Madam

I am directed to refer this Ministry's letter No. 32-7/2014 dated 8th April, 2015 on the above mentioned subject.

2. The Central Government, keeping in view the spread of COVID-19 virus in India and the declaration of COVID-19 as pandemic by the World Health Organisation (WHO), by way of a special one time dispensation, has decided to treat it as a notified disaster for the purpose of providing assistance under SDRF. A list of items and norms of assistance for containment of COVID-19 Virus in India eligible from SDRF is annexed.

Yours faithfully,
(Sanjeev Kumar Jindal)
Joint Secretary to Government of India
Tel : 23438096

Copy to AS(UT), MHA for making similar provisions for utilization of UT Disaster Response Funds by the Union Territories.

CC for information : PS to HM/MOS(N)/HS"

65. After issuance of the above notification, the Government of India, Ministry of Home Affairs (Disaster Management Division) issued order of 03.04.2020 on the subject:"Advance release of Central share from State Disaster Risk Management Fund (SDRMF) for the year 2020-21". By the said order the Central Government has released first instalment of Rs. 11,092/- crores out of Rs. 22,184/- crores which was the Central Share of SDRMF. All States have been allocated different amounts for the purpose of providing assistance under SDRMF. Annexure to the said notification is at page 161, which indicates that maximum grant allocated was to the State of Maharashtra as Rs. 1,611/- crores as first instalment and minimum amount to State of Goa, i.e., Rs. 6/- crores by the Centre. The notification dated 14.03.2020 clearly permits providing the assistance under SDRMF for COVID-19. In event, any State expenditure is in excess of the balance in the State's SDRMF, the State is entitled for the release of fund from NDRF as it is clear from new guidelines filed at pages 154 to 158 of the writ petition. The submission of the petitioner that NDRF cannot be used for any assistance for COVID-19, thus, cannot be accepted.

66. There is one more aspect of the matter which needs to be noted. When the Centre is providing financial assistance to the State to take measures to contain COVID-19, as we have noticed above that by order dated 03.04.2020 first instalment of Rs. 11,092/- crores which is the Central Share to the SDRMF has been given and there is nothing on record that any State has exceeded the expenditure in excess of the balance in the State's SDRMF, there is no occasion of asking more fund by the State from NDRF. When the Central Government is providing financial assistance to the States to contain COVID-19 it is not for any PIL petitioner to say that Centre should give amount from this fund or that fund. The financial planning is in the domain of the Central Government, which financial planning is made after due deliberation and consideration. We, thus, do not find any substance in the submission of the petitioner that there is any statutory restriction/prohibition in utilization of NDRF for COVID-19. More so when sub-section (2) of Section 46 specifically provides that NDRF shall be made available to the National Executive Committee to be applied towards meeting the expenses for emergency response, relief and rehabilitation in accordance with the guidelines laid down by the Central Government, the NDRF can be used for containment of COVID-19.

67. Further as observed above, it is for the Central Government to take the decision as from which fund what financial measures are to be taken and it is neither for PIL petitioner to claim that any financial assistance be made from particular fund nor this Court to sit in judgment over the financial decisions of the Central Government.

68. The PM CARES Fund is a public charitable trust and is not a Government fund. The charitable trusts are public trusts. Black's Law Dictionary, Tenth Edition defines charitable trust in following words:

"charitable trust. A trust created to benefit a specific charity, specific charities, or the general public rather than a private individual or entity. Charitable trusts are often eligible for favorable tax treatment."

69. The mere fact that administration of the Trust is vested in trustees, i.e., a group of people, will not itself take away the public character of the Trust as has been laid down in *Mulla Gulam Ali & Safiabai D. Trust* v. *Deelip Kumar & Co.*, (2003) 11 SCC 772. In paragraph 4, this Court laid down:

"4. The mere fact that the control in respect of the administration of the Trust vested in a group of people will not itself take away the public character of the Trust....."

70. The contributions made by individuals and institutions in the PM CARES Fund are to be released for public purpose to fulfill the objective of the trust. The PM CARES Fund is a charitable trust registered under the Registration Act, 1908 at New Delhi on 27.03.2020. The trust does not receive any Budgetary support or any Government money. It is not open for the petitioner to question the wisdom of trustees to create PM CARES fund which was constituted with an objective to extend assistance in the wake of public health emergency that is pandemic COVID-19.

71. Shri Dave during submissions has fairly submitted that he is not questioning the bona fide of

constitution of PM CARES Fund. His submission is that NDRF is audited by CAG but PM CARES Fund is not audited by CAG rather by a private Chartered Accountant. The nature of NDRF and PM CARES Fund are entirely different. The guidelines issued under Act, 2005 with regard to NDRF specifically provides for audit of the NDRF by the Comptroller & Auditor General of India whereas for public charitable trust there is no occasion for audit by the Comptroller & Auditor General of India.

72. We may notice one more aspect with regard to COVID-19. We have noticed above that guidelines which were issued for constitution and administration of NDRF and State's SDRMF, the guidelines provided utilization of fund for limited calamities, which did not include any biological and public health emergency. We have already noticed Clause 3.1 of guidelines for administration of NDRF, which did not provide for the calamities which cover the biological and public health emergency. Thus, under the guidelines which were in existence with effect from financial year 2015-16 neither NDRF nor SDRF covered the biological and public health emergencies. It was only by notification dated 14.03.2020 that COVID-19 was treated as notified disaster for the purpose of providing assistance under SDRF. Obviously prior to this notification dated 14.03.2020 no contribution by any person or institution in the NDRF could have been made with respect to specified disaster, namely, biological and public health emergency like COVID-19, Outbreak of COVID-19 in India as well as other countries of the World required immediate enhancement in the infrastructure of medical health and creation of fund to contain COVID-19. At this need of the hour no exception can be taken to the constitution of a public charitable trust, namely, PM CARES Fund to have necessary financial resources to meet the emergent situation.

73. The NDRF and PM CARES Fund are two entirely different funds with different object and purpose. In view of the foregoing discussions, we answer question Nos. 3, 4 and 5 in following manner:

Answer 3. The Union of India can very well utilize the NDRF for providing assistance in the fight of COVID-19 pandemic by way of releasing fund on the request of the States as per new guidelines.

Answer 4. Any contribution, grant of any individual or institution is not prohibited to be credited into the NDRF and it is still open for any person or institution to make contribution to the NDRF in terms of Section 46(1)(b) of the Act, 2005. The contribution by any person or by any institution in PM CARES Fund is voluntary and it is open for any person or institution to make contribution to the PM CARES Fund.

Answer 5. The funds collected in the PM CARES Fund are entirely different funds which are funds of a public charitable trust and there is no occasion for issuing any direction to transfer the said funds to the NDRF.

74. In view of the foregoing discussions, the prayer ‘a’ and ‘b’ made in the writ petition are refused. With respect to prayer ‘c’, we make it clear (i) that there is no statutory prohibition for the Union of India utilizing the NDRF for providing assistance in the fight of COVID-19 in accordance with the guidelines issued for administration of NDRF; (ii) there is no statutory prohibition in making any contribution by any person or institution in the NDRF as per Section 46(1)(b) of the Act, 2005.

75. The prayer of the petitioner to direct all the funds collected in the PM CARES Fund till date to be transferred to the NDRF is refused.

76. Subject to clarification of law as made above, the writ petition is dismissed.
