

SECTION:PIL

IN THE SUPREME COURT OF INDIA
(CIVIL ORIGINAL WRIT JURISDICTION)

I.A. NO. _____ OF 2021

IN

WRIT PETITION (CIVIL) NO. 607 OF 2021

IN THE MATTER OF:

DR. JACOB PULIYEL

....PETITIONER

VERSUS

UNION OF INDIA & ORS.

....RESPONDENTS

FILING INDEX

S.NO.	PARTICULARS	COPIES	C.FEE
1.	APPLICATION FOR DIRECTION WITH AFFIDAVIT	1	120/-
2	ANNEXURE A1 TO P38	1	NIL

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PAPER-BOOK

(FOR INDEX KINDLY SEE INSIDE)

(APPLICATION FOR DIRECTION)

COUNSEL FOR THE PETITIONER: **PRASHANT BHUSHAN**

INDEX

S. NO.	PARTICULARS	PAGES
1.	Application for Direction with affidavit on behalf of Petitioner with Affidavit	1-36
2.	Annexure-A1: A copy of the LiveMint news report dated 01.04.2021 titled "Brazilian regulator rejects Covaxin on violation of norms"	37-39
3.	Annexure-A2: A copy of the Hindustan Times news report dated 11.06.2021 titled "Why was Bharat Biotech's Covaxin not approved in US? Here's what we know so far"	40-42
4.	Annexure-A3: A copy of the Hindu news report dated 23.05.2021 titled "India to push for Covaxin recognition by WHO and EU"	43-46
5.	Annexure-A4: A copy of the Quint news report dated 09.02.2021 titled "Explained: Is the Data From Covaxin Trial's Bhopal Site Tainted? Q&A on how Covaxin's Bhopal trial was to be conducted"	47-61
6.	Annexure-A5: A copy of the Mint Report dated 04.06.2021 titled "US students who took Covaxin, Sputnik V, asked to get re-vaccinated"	62-65
7.	Annexure-A6: A copy of the Aljazeera report dated 15 th March 2021, titled "Which countries have stopped using Astra Zeneca's Covid vaccine?"	66-71
8.	Annexure-A7: A copy of the Ministry of Health and Family Welfare's Operational Guidelines for COVID-19 Vaccine dated 28.12.2020	72-73

9.	Annexure-A8: A copy of Covaxin's Phase III Trial data published by CTIRI	74-82
10.	Annexure-A9: A copy of the RTI reference no. MOHFW/R/T/21/00987 dated 21.04.2021	83
11.	Annexure-A10: A copy of the Zee Media Bureau dated 09.06.2021 titled "No more mandatory negative COVID-19 RT-PCR report for train travel? Check what Indian Railways is planning"	84-85
12.	Annexure-A11: A copy of the office of the District Development Commissioner's order (Ref. No. DDCKCPO/2020-21/Health/4745-4800) dated 17.06.2021	86
13.	Annexure-A12: A copy of the India Today Report titled "West Bengal: Covid vaccination certificates mandatory to enter parks but not hotels, malls" dated 17.06.2021	87-88
14.	Annexure-A13: A copy of the office of the Department of Space, Indian Space Research Organisation's Satish Dhawan Space Centre's order (Ref.No.CON/2(2)/2021) dated 06.06.2021	89
15.	Annexure-A14: A copy of Bharat Heavy Electricals Limited, Tiruchirappalli's circular dated 13.06.2021	90-91
16.	Annexure-A15: A copy of Deputy Commissioner of West Garo Hills, Tura, Meghalaya's order dated 08.06.2021	92
17.	Annexure-A16: copy of Deputy Commissioner of East Khasi Hills, Meghalaya's order dated 12.06.2021	93-94

18.	Annexure-A17: A copy of Chief Secretary, Nabanna, West Bengal's order dated 14.06.2021	95-96
19.	Annexure-A18: A copy of the Government Of Meghalaya Office Of The Deputy Commissioner, Ri Bhoi District, Nongpoh Order (Memo.No.Ddma.Rb /173/2021/29-A) dated 08.06.2021	97
20.	Annexure-A19: A copy of the Government of Puducherry's State Executive Committee Order (No. 104/PSEC/COVID19/2021) dated 07.06.2021	98-103
21.	Annexure-A20: A copy of the Southern Railways Order by the Sr. DCM/TVC dated 08.04.2021	104
22.	Annexure-A21: A copy of Prism Johnson Limited, Karaikal's order dated 16.06.2021	105
23.	Annexure-A22: A copy of Sri Ramachandra Institute of Higher Education and Research's order dated 17.06.2021	106-108
24.	Annexure-A23: A copy of the Business Today report dated 02.06.2021 titled "COVID-19: No salary without vaccination for govt employees in this UP district"	109-110
25.	Annexure-A24: A copy of the Indian Express report dated 10.06.2021 titled "In MP, those not vaccinated get tagged with skull mark, a warning"	111-113
26.	Annexure-A25: A copy of the Notice dated 11.05.2021	114
27.	Annexure-A26: A copy of the Notice dated 19.05.2021	114

28.	Annexure-A27: A copy of the Times of India Report titled "Max Life, Tata AIA Make Vaccination Must for Term Life"	116
29.	Annexure-A28: A copy of the Government of Meghalaya Order No.DSEO/WKH/COVID-19/583/2020/ 429 dated 10.05.2021	117
30.	Annexure-A29: A copy of the Patrika News Network Report titled "Health department seeks report of vaccination of education department staff If not vaccinated, then no salary"	118
31.	Annexure-A30: A copy of the NDTV reported dated 10 th June 2021 titled, "Delta Variant Predominant Despite Complete, Partial Vaccination: Study"	119-122
32.	Annexure-A31: A copy of the Hindustan Times report dated 10 th June 2021, titled 'Indiscriminate vaccination can lead to rise of mutant strains': Experts tell PM"	123-125
33.	Annexure-A32: A copy of the report on the NIH website "Lasting Immunity found after recovery from COVID-19" dated January 26 2021	126-129
34.	Annexure-A33: A copy of The Wire report dated 9 th April 2021 "617 serious adverse events after vaccination reported in India until March 29"	130-133
35.	Annexure-A34: A copy of the Vaers report of Covid vaccine adverse events in the US as shown on its website	134-135
36.	Annexure-A35: A copy of an article in The Daily Expose dated, 19 th June 2021 detailing the Covid vaccine Adverse events in the UK	136-143

37.	Annexure-A36: A copy of a report in Vaccine Impact dated 21 st June 2021 detailed Covid vaccine adverse reactions	144-148
38.	Annexure-A37: A copy of the Gujarat High Court order dated 22 nd June 2021	149
39.	Annexure-A38: A copy of the High Court order dated 23 rd June 2021	145-157

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**APPLICATION FOR DIRECTION ON BEHALF OF THE
PETITIONER**

1. That the petitioner has filed the instant writ petition under Article 32 of the Constitution of India for the enforcement of fundamental rights under Article 14 and 21 of the Constitution of India, seeking a writ directing the respondents to make public the segregated data of the clinical trials for the vaccines that are being administered to the population in India under the Emergency Use Authorization granted by the Drugs Controller General of India (DCGI). Further the petitioner has prayed that no coercive mandates for use of these inadequately tested vaccines may be issued and that the courts reiterate that vaccine mandates are repugnant to the right of humans to autonomy and right to self-determine what may be injected into their bodies. In so doing this Hon'ble Court would uphold the rights

of individuals to give informed consent as the Delhi High Court did, in the Measles Rubella case. It is submitted that coercing citizens directly or indirectly to get vaccinated is unconstitutional and violates the Right to Life of citizens. While the government has clearly stated in numerous RTIs that Covid vaccines are voluntary, there are many instances from across the country where now various authorities are mandating the vaccines for opening shops, retaining employment, entering educational and other premises, etc. In light of these continuing mandates the petitioner is forced to file this application.

2. Quite apart from the fact that no vaccines however safe and efficacious they may be, can be forced upon people in this manner, the fact is that the Covid vaccines being administered and mandated in India have not even been tested in accordance with the rules and protocol and have been only given emergency use authorization in exceptional circumstances without full testing by the Drug Controller General of India. With the roll out of these vaccines in the mass immunization programme in India as well as in other countries, it is now becoming increasingly clear that these vaccines do have serious side effects and their efficacy especially against new variants is doubtful. Various countries have either rejected or halted the use of the vaccines Covaxin and Astra Zeneca vaccines in their immunization programmes.

Covaxin and Astra Zeneca (Covishield in India) rejected by various countries and authorities

3. Bharat Biotech's Covaxin was rejected by Brazil's drug regulator Anvisa because of violations of norms for good manufacturing practices. According to the report by the regulator Bharat Biotech had skipped key steps in ensuring that the SARS-COV-2 virus in the vaccine was fully killed, or was incapable of multiplying in the human body. This created the very real risk that some batches of Covaxin could give people the disease they were to protect against. Based on the report, Brazil suspended its order of 20 million Covaxin doses from Bharat Biotech.

"Brazil's drug regulator Anvisa has rejected Bharat Biotech International's application for supplying Covaxin in the country after an inspection of the company's facility at Hyderabad in March found violations of norms for good manufacturing practices.

During the inspection, different non-conformities were found, which denote a significant risk to manufacturing and product quality assurance, implying a health risk for users, the regulator said on Tuesday.

Anvisa, short for Agencia Nacional de Vigilancia Sanitari, said that Bharat Biotech has not validated the method used to inactivate, or kill, the virus, which may cause contamination of patients with the Sars-CoV2 virus itself. This is related to product safety, it said.

The regulator also pointed to lack of specific control methods to quantify the antigen content and potency of the vaccine, which may lead to variations in antigen content and consequently compromise its effectiveness. It also flagged lack of controls to guarantee the sterility and purity of the vaccine, both of which could affect its safety.”

(A copy of the LiveMint news report dated 01.04.2021 titled “Brazilian regulator rejects Covaxin on violation of norms” is annexed as **Annexure A1 (Page 37 to 39)**).

4. The United States FDA denied approval to Covaxin because of lack of appropriate clinical data:

“Covaxin, Bharat Biotech's India-made vaccine against the coronavirus disease (Covid-19), was not given approval for emergency use in the United States by the country's top public health regulator -- the Food and Drug Administration (FDA). Rejecting Covaxin's application for emergency use authorisation in the US, the FDA sought more data on the clinical trials for the vaccine, the complete extent of which is still lacking.”

(A copy of the Hindustan Times news report dated 11.06.2021 titled “Why was Bharat Biotech's Covaxin not approved in US? Here's what we know so far” is annexed as **Annexure A2 (Page 40 to 42)**).

5. More significantly, Covaxin was still due to be approved by the WHO on 23rd May 2021:

“The notification alongside the Covaxin application confirms that the application, or Expression of Interest, was received on April 19 this year, but that “more information [is] required”, and that a pre-submission meeting prior to the EUL assessment would be planned in “May-June 2021”. According to sources, the WHO is awaiting Bharat Biotech’s Phase-3 final analysis data.”

(A copy of the Hindu news report dated 23.05.2021 titled “India to push for Covaxin recognition by WHO and EU” is annexed as **AnnexureA3 (Page 43 to 46)**.)

6. The Quint reported several worrying ethical breaches in the clinical trials for Covaxin:

“In January 2021, several media outlets carried reports of worrying ethical breaches at People’s Hospital – the Bhopal site of Bharat Biotech’s phase 3 trial for Covaxin. The claimed breaches ranged from luring participants (by not clearly telling them they were part of a clinical trial, and not a vaccination drive) to not treating the participants when they fell sick during the course of the trial.

Now, a copy of the protocol of the Covaxin phase 3 trial, which The Quint has reviewed, shows that People’s Hospital also

violated this protocol, tainting the integrity of data from the site. Several experts The Quint spoke to said such protocol violations, together with already documented violations of the New Drug and Clinical Trial Rules 2019 (NDCT 2019), render the data from the site untrustworthy. This, in turn, will impact Bharat Biotech's calculations of the efficacy and safety of Covaxin from all of the 26 trial sites at the end of the study."

(A copy of the Quint news report dated 09.02.2021 titled "Explained: Is the Data FromCovaxin Trial's Bhopal Site Tainted? Q&A on how Covaxin's Bhopal trial was to be conducted" is annexed as **Annexure A4 (Page 47 to 61)**).

7. A Mint article dated 4th June 2021 details how Cavaxin and Sputnik V are not accepted in US Universities:

"Washington: Since March, over 400 US colleges and universities have announced students get Covid-19 vaccinations, ahead of the Autumn semester but those who have been inoculated with India's indigenous Covaxin or the Russian-made Sputnik V are being asked to re-vaccinate as these vaccines have not yet been approved by the World Health Organization (WHO)....are proposing different measures, out of which the more complicated scenario is if students received a vaccine that has not been approved by the WHO, like Sputnik or Covaxin. Many colleges are proposing that those

students will need to be revaccinated, which presents both medical and logistical conundrums.”

(A copy of the Mint Report dated 04.06.2021 titled “US students who took Covaxin, Sputnik V, asked to get re-vaccinated” is annexed as **Annexure A5 (Page 62 to 65)**).

8. 16 countries, mostly in Europe, have stopped using Astra Zeneca’s Covid Vaccine over concerns of blood clotting among receipts of the vaccine. These countries include Denmark, Norway, Germany, France, Italy, Spain, Iceland, Bulgaria, Ireland, The Netherlands, Cyprus, Portugal, Latvia, Sweden, Luxembourg and Canada.

(A copy of the Aljazeera report dated 15th March 2021, titled “Which countries have stopped using Astra Zeneca’s Covid vaccine?” is annexed as **Annexure A6 (Page 66 to 71)**).

Violation of Operational Guidelines for Covid Vaccine development

9. In the Ministry of Health and Family Welfare’s Operational Guidelines for COVID-19 Vaccine published on 28th December 2020, the phases of vaccine development are listed as:

“The Development of a vaccine is a time-consuming process that includes the following phases:

Table. 2.1. Phases of vaccine development

<i>Phases of vaccine</i>	<i>Purpose</i>
---------------------------------	-----------------------

<i>development/trial</i>	
<i>Pre-clinical</i>	<i>Vaccine development in laboratory</i>
<i>Phase 1 Clinical trial (8-10 participants)</i>	<i>For testing vaccine safety</i>
<i>Phase 2 Clinical trial (50-100 participants)</i>	<i>For testing vaccine immunogenicity i.e. production of antibodies against virus</i>
<i>Phase 3 Clinical trial (30,000-50,000 participants)</i>	<i>For testing actual protection offered by the vaccine</i>

The vaccine development process has been fast-tracked and multiple platforms are under development.

Among those with the greatest potential for speed are DNA and RNA-based platforms, followed by those for developing recombinant-subunit vaccines. RNA and DNA vaccines can be made quickly because they require no culture or fermentation, instead use synthetic processes. Per the tracker developed by the Vaccine Centre at the London School of Hygiene and Tropical Medicine, a total of 274 candidate vaccines are in different stages of development as of 4 December 2020,

preclinical (215), phase I (25), phase I/II (17), phase II (5), phase II/III (1), phase III (10) and licensed (1).”

(A copy of the Ministry of Health and Family Welfare’s Operational Guidelines for COVID-19 Vaccine dated 28.12.2020 is annexed as **Annexure A7 (Page 72 to 73)**).

10. According to the trial details published by CTRI for Covaxin’s Phase III trials, the participant sample size was 25,800. This does not even meet the lower limit (i.e. 30,000) of the sample size prescribed by the Ministry of Health and Family Welfare in its Operational Guidelines annexed above.

(A copy of Covaxin’s Phase III Trial data published by CTRI is annexed as **Annexure A8 (Page 74 to 82)**).

Illustrative Orders mandating vaccines

11. Multiple orders have been issued by public and private institutions across the country, mandating vaccines for continued employment or to shop shops or to access educational institutions, etc. These mandates amount to coercing citizens to get vaccinated despite the government having claimed that the vaccination programme is voluntary.

12. In an RTI query (reference MOHFW/R/T/21/00987) filed by Ramkumar on 21-04-2021 to the Ministry of Health and Family Welfare, the reply dated 04-05-2021 stated that the vaccination is not mandatory:

“Vaccination for COVID-19 is voluntary. However, it is advisable to receive the complete schedule of COVID-19 vaccine for protecting oneself against this disease and also to limit the spread of this disease to the close contacts including family members, friends, relatives and co-workers. Vaccination for COVID-19 is voluntary, therefore, no one can be deprived of any kind of Government service/facility/schemes due to not taking COVID vaccination.” **(Emphasis added)**

(A copy of the RTI reference no. MOHFW/R/T/21/00987 dated 21.04.2021 is annexed as **Annexure A9 (Page 83)**).

13. A news report by Zee Media Bureau dated 9th June 2021 details a new vaccine requirement policy for rail travel:

“As per sources, instead of a COVID-19 report, the Indian Railway is mulling to allow train passengers with a COVID-19 vaccination certificate. A person can also show his/her certificate through the AarogyaSetu app.”

(A copy of the Zee Media Bureau dated 09.06.2021 titled “No more mandatory negative COVID-19 RT-PCR report for train travel? Check

what Indian Railways is planning” is annexed as **Annexure A10 (Page 84 to 85)**.

Government orders mandating Vaccination, Non-Compliance: Salary Cuts and other Arbitrary Orders

14. The Office of the District Development Commissioner, Kathua (of the UT of Jammu and Kashmir) on 17th June 2021 released an order for vaccine compliance and prescribed the following strict measures to ensure adherence:

"1. All the Govt employees will get themselves compulsorily vaccinated before 30 June 2021.

2. The concerned DDO will not draw the salary of the employees of his/her office unless they have got themselves vaccinated (except those who are contraindicative for the same).

3. A certificate will be recorded by the concerned DDO certifying that the salary bills of only those employees have been presented In the Treasury who have to get themselves vaccinated.

4. The Treasury Officer will entertain the salary bills only after the above certificate of DDOs attached with the salary bills."

(A copy of the office of the District Development Commissioner's order (Ref. No. DDCKCPO/2020-21/Health/4745-4800) dated 17.06.2021 is annexed as **Annexure A11 (Page 86)**).

15. An India Today report detailed that entry in parks in West Bengal will only be allowed upon production of a vaccination certificate:

"West Bengal Chief Minister Mamata Banerjee on Monday extended the Covid lockdown in the state till July 1. However, she announced some relaxation to the curbs. One such relaxation is that parks have been permitted to open for three hours in the morning. However, those who want to enter will have to show proof of having taken two doses of the Covid-19 vaccine. The government notification reads, "Parks may remain open for morning walks, physical exercise etc from 6 am to 9 am and only vaccinated people shall be allowed."

(A copy of the India Today Report titled "West Bengal: Covid vaccination certificates mandatory to enter parks but not hotels, malls" dated 17.06.2021 is annexed as **Annexure A12 (Page 87 to 88)**).

16. Multiple government offices have vaccination guidelines for their staff members. ISRO's directive read as follows:

"1. Those employees who have completed 2 doses of vaccination, employees who have completed 14 days gestation

period after 1st dose of vaccination and employees who were affected by COVID 19 within three month and fully recovered shall be allowed to attend for duties.

2. Employees who could not vaccinated due to medical reasons are directed to consult the physicians of SHAR and SDM Hospitals and produce the medical certificate for exemption of vaccination on medical grounds to the respective entity chiefs for further directions.

3. Those Employees who are not willing to get vaccinated are directed to produce COVID 19 RT-PCR negative report on every first working day of the week to the concerned Entity Chief for attending the duties.”

(A copy of the office of the Department of Space, Indian Space Research Organisation’s Satish Dhawan Space Centre’s order (Ref.No.CON/2(2)/2021) dated 06.06.2021 is annexed as **Annexure A13 (Page 89)**).

17. Bharat Heavy Electricals Limited in Tiruchirappalli issued a vaccine compliance directive and warned of administrative action against those who fail to comply:

“Appropriate action as deemed fit will be initiated against those employees who fail to get vaccinated on or before 28/06/2021 without valid reasons.

All are once again directed to get vaccinated themselves on or before 28.06.2021 without fail and protect yourselves, your family, co-employees and society at large from the infection/severity of Covid - 19."

(A copy of Bharat Heavy Electricals Limited, Tiruchirappalli's circular dated 13.06.2021 is annexed as **Annexure A14 (Page 90 to 91)**).

18. The Deputy Commissioner of West Garo Hills, Tura, Meghalaya issued a directive for vaccine compliance with a clause directing those failing to comply to avail earned leave:

"It has been brought to the knowledge of the undersigned that some of the Govt. employees of different offices of West Garo Hills District who are above 45 years of age have not been vaccinated till date. They are, therefore directed to get vaccinated or submit RTPCR Negative Test Report every 10 (ten) days with immediate effect to the concerned authorities. If, anyone is found Positive Case, they are directed to avail Earned Leave accordingly."

(A copy of Deputy Commissioner of West Garo Hills, Tura, Meghalaya's order dated 08.06.2021 is annexed as **Annexure A15 (Page 92)**).

19. The Office of the Deputy Commissioner of East Khasi Hills, Meghalaya directed shops to display the vaccination status of their staff in a prominent poster:

"a) Only Stand-Alone Shops are permitted to open and not Complexes/Malls.

b) All shops will place a prominent sign/poster indicating vaccination status of the staff/sales person.

c) Shops are encouraged to opt for home-delivery of items, whenever possible."

(A copy of Deputy Commissioner of East Khasi Hills, Meghalaya's order dated 12.06.2021 is annexed as **Annexure A16 (Page 93 to 94)**).

20. In West Bengal, a COVID order issued the following directives for vaccine compliance:

*"11. All production units and industries including IT&ITES sector may function with 50% of total strength in each shift **subject to vaccination of employees**, wearing of masks and maintenance of physical distancing. Employers shall make transport arrangements from their end and obtain e-passes from Kolkata Police/District Administration.*

*12. Parks may remain open for morning walks, physical exercise etc during 6AM to 9AM and **only vaccinated people shall be allowed.....***

*19. Indoor/outdoor shooting and associated activities related to TV programmes and cinema may resume with not more than 50 persons per unit at a time, **subject to vaccination**, wearing of masks, maintenance of physical distancing and with own transport arrangements and e-passes from Kolkata Police/ District Administration.....*

***Employers/ management bodies/owners/ supervisors** of above mentioned work places shall be responsible for provisioning of all COVID safety measures including regular sanitization of work places, **vaccination of employees and for compliance of stated directives** and COVID appropriate norms. Employers shall make transport arrangements for their staff and employees from their own end. Work from home must be encouraged as far as possible and practical...*

*District administration, police commissionerates and local authorities shall ensure strict compliance of the stated directives. **Any violation of the aforesaid restriction measures will be liable to be proceeded against as per the provisions of Disaster Management Act, 2005 and under Indian Penal Code.** (Emphasis added)*

(A copy of Chief Secretary, Nabanna, West Bengal's order dated 14.06.2021 is annexed as **Annexure A17 (Page 95 to 96)**).

21. The Deputy Commissioner of Ri Bhoi, Meghalaya issued instructions to the effect of listing a set of liabilities for those not vaccinated against COVID-19:

“In view of the surging cases and 43 deaths due to Covid-19 without vaccination in the District and it has come to the notice of the undersigned that many Government Officials and staff in the District have not been vaccinated, hence, for the safety of everyone in the office and for those field staff interacting with the public especially, mother & children L. Smt. R.M. Kurbah, IAS, Deputy Commissioner Ri Bhoi District, Nongpoh do hereby issue the following instructions:

1. All Officials & staff are to get themselves vaccinated. If not vaccinated, they are to produce RTPCR Testing Certificate every 10 days. The test to be borne by the staff concerned.
2. All ASHAs/AWWs are to get themselves vaccinated. If not vaccinated, they are to produce RTPCR Testing Certificate every 10 days. The test to be borne by the staff concerned.
3. All shopkeepers are allowed to open their shops only after vaccination.
4. All drivers are considered Frontline Workers; hence, they are not allowed to ply without vaccination.
5. Teachers are to get themselves vaccinated as they will be in contact with the school children.”

(A copy of the Government Of Meghalaya Office Of The Deputy Commissioner, Ri Bhoi District, Nongpoh Order (Memo.No.Ddma.Rb/173/2021/29-A) dated 08.06.2021 is annexed as **Annexure A18 (Page 97)**).

22. According to a Government of Puducherry's State Executive Committee Order (No. 104/PSEC/COVID19/2021) dated 07.06.2021:

"6. (a) All shops owners and persons working in shops / commercial establishment industries are directed to get themselves vaccinated within 15 days, failing which they will not be allowed to function.

(b) Violation of restrictions/lockdown orders/ norms for containment zones by a shop/ commercial establishment/ industry shall be fined to a maximum level as permissible under the laws applicable.

(c) Violation of the lockdown order by stepping out of the home without any valid reason/ without identity card shall be fined.

(d) Any person violating the aforesaid lockdown or the National Directives will be liable to be proceeded against as per provision of 51 to 60 of Disaster Management Act and section 188 of IPC and other legal provisions as warranted."

(A copy of the Government of Puducherry's State Executive Committee Order (No. 104/PSEC/COVID19/2021) dated 07.06.2021 is annexed as **Annexure A19 (Page 98 to 103)**).

23. The Sr. DCM/TVC of the Southern Railways issued the following directive in an order dated 08.04.2021:

- “1. All commercial staff (CC, TC, ECRC, CCTC) of age above 45 shall take covid vaccination within the next 72 hours.
2. From 12/04/21 onwards Supervisors shall permit staff for duty only on production of vaccination certificate.
3. Staff who has not taken vaccination till 11/04/21 shall go on their own leave till get vaccinated.”

(A copy of the Southern Railways Order by the Sr. DCM/TVC dated 08.04.2021 is annexed as **Annexure A20 (Page 104)**.)

Private Mandates

24. Prism Johnson Limited, Karaikal issued a notice as per the instructions of Karaikal Collector and Factory Inspector barring non-vaccinated workers entry:

"As per the instruction of Karaikal Collector and Factory Inspector all are advised to put the first dose of coVID vaccine on or before 21.06.2021. Those who have taken their vaccine kindly share the hara copy of the certificatte to time office at the earliest since the same has to be submitted to the office of Inspector of Factories. Those who have not vaccinated will not be allowed to the entre the factory from 22.06.2021. As per the order of the Government.

Enclosures : The order of the Collector”

(A copy of Prism Johnson Limited, Karaikal’s order dated 16.06.2021 is annexed as **Annexure A21 (Page 105)**)

25. Sri Ramachandra Institute of Higher Education and Research, Chennai provided guidelines for vaccine compliance to the effect of:

“As per the Vice-Chancellor's Circular No.055/VC/2021 dated 16th June 2021 it is notified that the onsite education for the students of all Faculties of the University will resume from 5th July 2021. The onsite sessions shall be used for practical training, while theory teaching will continue online.

Accordingly, all the students are instructed to submit the following at the time of attending classes on 5th July 2021

FOR DAY SCHOLARS

Vaccination Certificate

If Vaccination Certificate is not submitted, RT-PCR Negative Certificate (with 72 hours validity) and an Undertaking (copy attached) to get vaccinated within a maximum period of one week are to be submitted.

FOR HOSTELLERS

• Vaccination Certificate is mandatory.”

(A copy of Sri Ramachandra Institute of Higher Education and Research’s order dated 17.06.2021 is annexed as **Annexure A22 (Page 106-108)**.)

26. Several of these orders detail blocking of salary of government employees for non-compliance of COVID-19 vaccination orders. The Business Today reported on 2nd June 2021 that the District Magistrate in Firozabad, Uttar Pradesh promulgated an oral order to stop the salaries of those government employees who have not been vaccinated:

“With a view to encourage COVID-19 vaccination, the district administration in Uttar Pradesh's Firozabad has ordered that government employees will not receive their salaries if they are not vaccinated.

District Magistrate Chandra Vijay Singh issued an oral order of "no vaccination, no salary", Chief Development Officer (CDO) Charchit Gaur said.

District treasury officer and other departmental heads have been given directions to implement the order and asked to make a list and ensure vaccination, Gaur said. As per the order, if an employee does not take COVID-19 vaccine, the department will initiate action and stop his/her salary for the month of May, he added. Government employees who are not vaccinated are trying to get their jobs so that their salaries are not withheld, Gaur said.”

(A copy of the Business Today report dated 02.06.2021 titled “COVID-19: No salary without vaccination for govt employees in this UP district” is annexed as **Annexure A23 (Page 109 to 110)**.)

27. An Indian Express report dated 10th June 2021 detailed how the police in Niwari, Madhya Pradesh made people wear posters according to the status of their vaccination status:

“At Prithvipur, in MP’s Niwari, police got people who were not vaccinated to wear posters with warnings. A NEWLY launched Covid vaccination drive in Madhya Pradesh’s Niwari district has led to policemen conducting checks on roads and making those who have not been vaccinated wear posters with skull marks — and the message: “*Mujhse dur rahein, maine abhi corona ka tikanahilagwaya* (Stay away from me, I haven’t got vaccinated for Covid).”

Those who are handed these posters, under the drive in the district’s Prithvipur block, are asked to read the message out loud and take an oath that they would get vaccinated within two days. Those who have been vaccinated are given badges with colours of the national flag and the message: “*Mein sacchadeshbhakthoonkyunkimaine corona ka tikalagwayahai* (I am a true patriot because I have been vaccinated).”

(A copy of the Indian Express report dated 10.06.2021 titled “In MP, those not vaccinated get tagged with skull mark, a warning” is annexed as **Annexure A24 (Page 111 to 113)**).

Educational Institutions and their Vaccine Mandates

28. An NGF College of Engineering notice dated 11.05.2021 mandates vaccination certificate:

"...We want you to feel confident in your decision to get vaccinated. The management has taken as a policy matter to protect everyone, Vaccination certificate is mandatory for your physical appearance in the institute."

(A copy of the Notice dated 11.05.2021 is annexed as **Annexure A25 (Page 114)**).

29. Parul University in its notice dated 19th May 2021 made all non-vaccinated students ineligible for "online classes":

"All the students in the university were informed to register for getting vaccination against Covid vide ref. (1). Many of the students have complied with this direction. Those students, who fail to register for vaccination up to May 29, 2021, will not be allowed to attend online classes from May 31, 2021. Shri. Jatin Vaidya, Principal, PPI is given the responsibility of identifying the students who have not registered for Covid Vaccination and inform the concerned teachers through their HOIs to not allow such students to attend online classes from May 31, 2021."

(A copy of the Notice dated 19.05.2021 is annexed as **Annexure A26 (Page 115)**).

Other Private Mandates

30. Several Insurance Providers have made COVID-19 vaccination mandatory for Life Insurance:

"Mumbai: Max Life and Tata AIA have taken the lead in asking for mandatory Covid-19 vaccine certificates for buyers of term life insurance-opening the doors for other insurers to follow suit to reduce future claims payouts, but depriving cover to those who have not yet been inoculated.

While Max Life is issuing term covers to people over the age of 45 only if they are able to produce their final vaccination certificates, Tata AIA is issuing policies, irrespective of age, only to those who have received their first shot.

The trigger for these conditions for issuing new term policies seems to have originated from reinsurers such as Munich Re and Swiss Re, who are the biggest underwriters of risk for the domestic insurance companies."

(A copy of the Times of India Report titled "Max Life, Tata AIA Make Vaccination Must for Term Life" is annexed as **Annexure A27 (Page 116)**)

Mandates for Teachers

31. Deputy Commissioner of West Khasi Hills district mandated all teachers to either get vaccinated or submit an RTPCR test every 10 days:

"In view of the rapid increase in the spread of Covid. 19 positive cases in the District, I am directed by the Deputy Commissioner, West Khasi Hills District, Nongstoin, vide letter No. COVID-19/MED-17/Pt.11/2021/8 dt. 8th May, 2021 to instruct all the teachers both Private and Government institutions to get themselves vaccinated. Since teachers have to mix around with students and other teachers, they are vulnerable for the spread of the Covid19 virus. Teachers are also required to assist the citizens who are 18+ age to register in the vaccination portal to enable them to get vaccination. Teachers who fail to take the vaccination should undergo RTPCR test every 10 days and should submit report showing that they are negative (free from covid. 19), failing which they should not be allowed to mix with the children in the schools and through contact tracing if they are found to be the carriers of Covid.19 they will be booked under the law."

(A copy of the Government of Meghalaya Order No.DSEO/WKH/COVID-19/583/2020/ 429 dated 10.05.2021 is annexed as **Annexure A28 (Page 117)**.)

32. Patrika News Network, a Hindi news daily, reports that Jabalpur's education department staff's salaries will be suspended until further notice upon non-vaccination. Following is a translated excerpt:

"The situation regarding vaccination has not yet been clarified in the education department. Hence, the Health Department has called for a report on the status of vaccination in the Education Department. The Health Department has clearly said that if any employee teacher has not been vaccinated so far, then their salary for the coming month should be stopped. Unless a certificate of Covid-19 vaccination is presented by him after getting vaccinated, his salary should not be released. This instruction must be followed. The certificate will have to be checked - the department said."

(A copy of the Patrika News Network Report titled "Health department seeks report of vaccination of education department staff If not vaccinated, then no salary" is annexed as **Annexure A29 (Page 118)**).

Recent studies have recommended against indiscriminate vaccination

33. A study conducted by AIIMS recently claimed that the presence of the Covid 19 Delta variant is predominantly found even after the first dose or both doses of the vaccine have been administered, raising

serious concerns regarding the effectiveness of these vaccines against variants.

"A preliminary study conducted by the All India Institute of Medical Science (AIIMS), Delhi claimed that the presence of COVID-19 Delta variant (B1.617.2) is predominantly found even after the first dose or both doses of vaccine has been administered.

The study included 63 people who got breakthrough infections; of which 36 patients received two doses, while 27 had received one dose of vaccine.

...

"Viral load at the time of diagnosis was high in all the patients irrespective of vaccination status or type of vaccine received. The initial course of disease with high-grade non-remitting fever lasted for five to seven days in the vaccinated group, similar to the clinical presentation in unvaccinated patients. During the subsequent course of illness, neither disease worsening (stable biomarkers) nor mortality was reported in the present group, confirming the previous observations," as per the study.

The presence of Delta variant was about 60 per cent of people who received a double dose of either vaccine and it was found in 77 per cent of people who received one dose."

(A copy of the NDTV reported dated 10th June 2021 titled, "Delta Variant Predominant Despite Complete, Partial Vaccination: Study" is annexed as **Annexure A30 at Page 119 to 122**).

34. Two groups of medical scientist including doctors from AIIMS and those in the national expert committee on Covid have warned against indiscriminate vaccination and that the vaccines themselves could be giving rise to the more infectious variants of COVID.

“A group of public health experts comprising doctors from All India Institute of Medical Sciences (AIIMS) and members from Covid-19 special taskforce on Thursday said that indiscriminate vaccination could lead to the rise of mutant strains, according to a news report by news agency PTI.

The study also highlighted that there is no need to vaccinate those who had been infected by Covid-19 previously and said that the vaccination of such individuals can be done after generating evidence that the vaccine is beneficial after natural infection.”

A copy of the Hindustan Times report dated 10th June 2021, titled ‘Indiscriminate vaccination can lead to rise of mutant strains’: Experts tell PM”, is **annexed as Annexure A31 at Page 123 to 125).**

35. The National Institutes of Health (NIH) in the United States of America, has now publicized results from a study funded by it, that the immune system of more than 95% of people who are recovered from COVID-19 has durable memories of the virus up to 8 months

after infection and hoping that vaccinated people would develop similar lasting immune memories after vaccination. Given this finding there is clearly no need to administer the vaccine to Covid recovered people. A report published on its website states,

“Several months ago, our studies showed that natural infection induced a strong response, and this study now shows that the responses last...We are hopeful that a similar pattern of responses lasting over time will also emerge for the vaccine-induced responses.”

(A copy of the report on the NIH website “Lasting Immunity found after recovery from COVID-19” dated January 26 2021 is annexed as **Annexure A32 (Page 126 to 129)**).

Serious adverse events reported post immunization

36. Though in India as of March 29 2021, 617 serious adverse events after vaccination were reported, it is well known that the adverse reporting system in India is far from adequate and underused. According to a presentation made before the National AEFI Committee, 617 cases were reported, 180 people died and of these, complete documents were available only for 35 people. According to a report in The Wire Science,

“The Government of India has been drawing flak for some time after it stopped publishing AEFI reports after February 26, around 40 days after the start of India’s COVID-19 vaccination

drive, and after a seemingly laidback response to concerns about AstraZeneca's shot, called 'Covishield' in India.

According to the slides presented on March 31, prepared by the Immunisation Technical Support Unit at the health ministry and which *The Wire Science* has seen, the ministry has ascertained the type of AEFI for 492 reports. Of them, 63 people didn't require hospitalisation, 305 people required hospitalisation and 124 people died. A little more than half of those who died did so due to acute coronary syndrome, which refers to any conditions that suddenly and significantly reduce blood flow to the heart, including heart attacks.

However, according to the presentation, complete documents were available for only 35 people. These documents refer to case reporting forms and case investigation forms that the corresponding healthcare workers must file at the district level for each case."

(A copy of The Wire report dated 9th April 2021 "617 serious adverse events after vaccination reported in India until March 29" is annexed as **Annexure A33 at Page 130 to 133**).

37. In the UK and the USA where the AEFI reporting systems are better functional, the USA has reported 5993 deaths and 3,58,379 adverse reactions from Covid vaccines till 11th June 2021 and the UK has reported 1332 deaths and 9,49,287 adverse reactions. The European Unions database of Adverse Drug Reactions for Covid-19 shows 15,472 death and 15,00,000 adverse reaction reported. Studies have shown that only 1-10% of adverse reactions are actually reports, suggesting that the actual number of adverse reactions and deaths is much higher.

(A copy of the Vaers report of Covid vaccine adverse events in the US as shown on its website is annexed as **Annexure A34 (Page 134 to 135)**).

(A copy of an article in The Daily Expose dated, 19th June 2021 detailing the Covid vaccine Adverse events in the UK is annexed as **Annexure A35 (Page 136 to 143)**).

(A copy of a report in Vaccine Impact dated 21st June 2021 detailed Covid vaccine adverse reactions is annexed as **Annexure A36 (Page 144 to 148)**).

High Court orders staying vaccine mandates

38. Various High Courts have taken cognizance of these forced vaccine mandates. The High Court of Gujarat has vide order dated 22nd June 2021, stayed the dismissal of the petitioner officer Shri Yogendra Kumar by the India Air Force, seeking an explanation from the Air Force.

“Notice returnable on 1.07.2021.

Till then, no coercive action shall be taken against the petitioner, who is at present not willing to take the vaccine.”

(A copy of the Gujarat High Court order dated 22nd June 2021 is annexed as **Annexure A37 (Page 149)**).

39. In an order dated 23rd June 2021, the Meghalaya High Court held that mandatory or forceful vaccination does not find any force in law leading to such acts being liable to be declared *ultra vires ab initio*

“Article 21 encompasses within its fold, right to health, as a fundamental right. By that same analogy, right to health care, which includes vaccination, is a fundamental right. However, vaccination by force or being made mandatory by adopting coercive methods, vitiates the very fundamental purpose of the welfare attached to it. It impinges on the fundamental right(s) as such, especially when it affects the right to means of livelihood which makes it possible for a person to live. As held in *Olga Tellis & Ors vs. Bombay Municipal Corporation & Ors* reported at AIR 1986 SC 180 = (1985) 3 SCC 545, right to life includes right to the means of livelihood. Any action of the State which is in absolute derogation of this basic principle is squarely affected by Article 19(1)(g). Although, Article 19(6) prescribes “reasonable restrictions” in the “interest of general public”, the present instance is exemplary and clearly distinguishable. It affects an individual’s right, choice and liberty significantly more than affecting the general public as such or for that matter, the latter’s interests being at stake because of the autonomous decision of an individual *human being* of choosing not to be vaccinated. It is more about striking the right balance between an individual’s right vis-à-vis the right of the public at large. However, in substantiation of Mill’s theory of the liberty to exercise one’s right until it impinges on the right of another; here too, the “welfare State” is attempting to secure the rights of others, which – though legitimate – is palpably excessive owing to the procedure adopted by it.

...In this case, there is a clear lack of legitimacy in prohibiting freedom of carrying on any occupation, trade or business amongst a certain category or class of citizens who are otherwise entitled to do so, making the notification/order ill-conceived, arbitrary and/or a colourable exercise of power. A

notification/order of the State certainly cannot put an embargo and/or fetter on the *fundamental* right to life of an individual by stripping off his/her right to livelihood, except according to the procedure established by law. Even that procedure is required to be reasonable, just and fair (see Olga Tellis, supra). Till now, there has been no legal mandate whatsoever with regard to coercive or mandatory vaccination in general and the Covid19 vaccination drive in particular that can prohibit or take away the livelihood of a citizen on that ground.

...Therefore, right to and the welfare policy for vaccination can never affect a major fundamental right; i.e., right to life, personal liberty and livelihood, especially when there exists no reasonable nexus between vaccination and prohibition of continuance of occupation and/or profession. A harmonious and purposive construction of the provisions of law and principles of equity, good conscience and justice reveals that mandatory or forceful vaccination does not find any force in law leading to such acts being liable to be declared *ultra vires ab initio*."

(A copy of the High Court order dated 23rd June 2021 is annexed as **Annexure A38 (Page 150 to 157)**).

40. In these circumstances the petitioner submits that any sort of coercion for these vaccines would not only be a violation of fundamental rights but a violation of any rational public health policy.

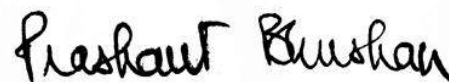
PRAYERS

In view of the above facts and circumstances, it is respectfully prayed that this Hon'ble Court may be pleased to pass the following ad-interim direction:-

- a. Restrain all authorities and institutions, public and private, from mandating the vaccine in any manner whatsoever as a precondition for accessing any service or on pain of any penalty.
- b. To pass any further order or orders, as this Hon'ble Court may deem fit and proper in the interest of justice.

FOR THIS ACT OF KINDNESS THE HUMBLE APPLICANT AS IN DUTY BOUND SHALL EVER PRAY.

PETITIONER THROUGH



(PRASHANT BHUSHAN)
COUNSEL FOR THE PETITIONER

NEW DELHI
DATED: 25.06.2021

ANNEXURE: A1**LiveMint****Brazilian regulator rejects Covaxin on violation of norms
Different non-conformities were found during inspection,
which risk to quality (AFP)**

Updated: **01 Apr 2021**, 12:05 AM IST

Leroy Leo

Bharat Biotech can reapply for the certification of its facilities after it completes the remediation process

Brazil's drug regulator Anvisa has rejected Bharat Biotech International's application for supplying Covaxin in the country after an inspection of the company's facility at Hyderabad in March found violations of norms for good manufacturing practices.

During the inspection, different non-conformities were found, which denote a significant risk to manufacturing and product quality assurance, implying a health risk for users, the regulator said on Tuesday.

Anvisa, short for Agencia Nacional de Vigilancia Sanitari, said that Bharat Biotech has not validated the method used to inactivate, or kill, the virus, which may cause contamination of patients with the Sars-CoV2 virus itself. This is related to product safety, it said.

The regulator also pointed to lack of specific control methods to quantify the antigen content and potency of the vaccine, which may lead to variations in antigen content and consequently compromise its effectiveness. It also flagged lack of controls to guarantee the sterility and purity of the vaccine, both of which could affect its safety.

In Brazil, Bharat Biotech tied up with Precisa Medicamentos for supply of vaccine directly to the government. The firm had provided an action plan to the regulator on 17 March, but Anvisa said that the measures adopted so far are not sufficient to mitigate risks associated with non-conformities.

Bharat Biotech has in the Brazilian firm's action plan proposed completion of studies and modifications to guarantee the safety and efficacy of the vaccine, Anvisa said. However, the regulator said that these will not have an impact on the efficacy and safety of what has been manufactured so far.

Bharat Biotech can reapply for the certification of its facilities and emergency use authorization after it completes the remediation process. "The requirements pointed out during inspection will be fulfilled. The timelines are under discussion and will be resolved,"

Bharat Biotech said, adding that the order for 20 million doses from Brazil is still active.

Gagandeep Kang, professor at Christian Medical College, said that the issues do not necessarily mean that the product has failed. "But these are things that the company has to take seriously and the Indian regulator should also take note and look into it," Kang added.

<https://www.livemint.com/news/india/brazilian-regulator-rejects-bharat-biotech-s-covaxin-on-violation-of-gmp-norms-11617192833754.html>

Prashant Kushan
(TRUE COPY)

ANNEXURE: A2

Hindustan Times

Why was Bharat Biotech's Covaxin not approved in US? Here's what we know so far Rejecting Covaxin's application for emergency use authorisation in the US, the FDA sought more data on the clinical trials for the Covid-19 vaccine.

By hindustantimes.com | Written by Joydeep Bose | Edited by Meenakshi Ray

PUBLISHED ON **JUN 11, 2021** 11:40 AM IST

Covaxin, Bharat Biotech's India-made vaccine against the coronavirus disease (Covid-19), was not given approval for emergency use in the United States by the country's top public health regulator -- the Food and Drug Administration (FDA). Rejecting Covaxin's application for emergency use authorisation in the US, the FDA sought more data on the clinical trials for the vaccine, the complete extent of which is still lacking. The FDA rejection would normally indicate a delay in Covaxin's launch in the US, but Bharat Biotech's US partner Ocugen Inc said on Thursday that it would instead push for a full US approval of the indigenous vaccine candidate Covaxin, without pursuing an emergency use authorisation.

The FDA requested additional information and data on Bharat Biotech's Covaxin, explained a statement by the Hyderabad-based pharma company's US partner Ocugen. Covaxin has been facing criticism back home in India for not sharing its Phase-3 trial data, despite being approved by India's top drug regulator, the Drugs Controller General of India (DCGI) six months ago.

The FDA rejected Bharat Biotech's proposal for emergency use approval of Covaxin, the Covid-19 vaccine, in the US because the company submitted partial trial data from March this year. According to an official statement, the FDA has asked Ocugen to submit additional trial data so that it can file for a Biologics Licence Application (BLA), which is a full approval, instead of the emergency use approval.

Revising its guidelines for emergency use authorisation, the US FDA earlier said that it will entertain no such new requests. Despite this, Ocugen remained hopeful last month that its Covaxin proposal would be considered by the FDA due to a series of discussions since late last year, the company informed its investors in a May 26 statement. "We believe that the FDA's new guidance confirms that Ocugen continues to meet all criteria for the submission of a EUA," the statement read.

Covaxin's lack of Phase-3 trial data

Bharat Biotech, which is currently carrying out the Phase-3 clinical trials for Covaxin, informed news agency ANI on Wednesday that it will make the data public during July, following which the company will be applying for full licensure of the Covid-19 vaccine. "Once data from the final analysis of phase III studies are available, Bharat Biotech will apply for full licensure for Covaxin," Bharat Biotech told the news agency.

Bharat Biotech added that Phase-4 trials are also being done to check the "real-world effectiveness" of the vaccines" and to meet scientifically approved standards for safety and efficacy.

Covaxin's faces hurdle with foreign approval

Bharat Biotech's Covaxin Covid-19 vaccine has been facing hurdles gaining foreign approvals since the Phase 3 trial data is essential for validation from the World Health Organization (WHO), which will allow the Hyderabad-based pharmaceutical company to export its Covid-19 vaccine and make it a part of the much-coveted "vaccine passport".

However, without the Phase 3 trial data, Covaxin has been facing remains unapproved in several countries, where it is failing to gain access in strictly regulated markets. At a time when authorisation from top health regulators at the US, the European Union, or the WHO is needed for a vaccine to cross borders, the India-made Covid-19 vaccine Covaxin remains unrecognised, as some foreign countries are even considering Indian students vaccinated with Covaxin as "unvaccinated". "We are aware that Bharat Biotech has sought the WHO emergency-use listing for Covaxin. We hope that the process of getting this approval is completed at an early date," said MEA spokesperson Arindam Bagchi at an online briefing on Thursday, speaking on the matter.

<https://www.hindustantimes.com/india-news/why-was-bharat-biotech-s-covaxin-covid-19-vaccine-not-approved-in-us-here-s-what-we-know-so-far-101623387176530.html>

Preshant Bhusan

(TRUE COPY)

ANNEXURE: A3**The Hindu**

India to push for Covaxin recognition by WHO and EU

Kallol Bhattacharjee

Suhasini Haidar

NEW DELHI, MAY 23, 2021 12:24 IST

WHO has recognised several vaccines from the makers like Oxford AstraZeneca, Pfizer and Moderna which enables the vaccine makers to export the doses worldwide.

Faced with concerns that Indians receiving the Covaxin vaccine may face travel restrictions, the government has decided to help ensure that Hyderabad-based Bharat Biotech receives clearances from both the World Health Organisation (WHO) and subsequently, the EU's European Medicines Agency (EMA).

According to sources, the Ministry of External Affairs (MEA) has been tasked with studying the matter, given both the need for recognition for the Indian-made vaccine, as well as the desire to push for more export orders in the future, and a team led by Foreign Secretary Harsh Shringla and officials from the Health Ministry are expected to meet with Bharat Biotech representatives on Monday.

"There is certainly an interest in getting Covaxin on WHO's Emergency Use List (EUL)," said an official familiar with the matter, adding that the

European regulatory procedures are likely to take longer but are also being pursued.

The decision comes as 27 EU member countries on Thursday approved a proposal to allow “fully vaccinated” tourists from countries outside Europe under certain criteria. While the Astra Zeneca vaccine Covishield would be included on the WHO and EU’s listings, if travel from India is accepted, those who have taken Covaxin would not.

Prime Minister Narendra Modi and members of the Cabinet are amongst those who have taken Covaxin doses. In addition, explained officials, getting Covaxin on the WHO’s EUL would be a big boost, and a first for an Indian-developed and produced vaccine.

Officials stressed that the EUL processes are technical in nature, and the MEA and the government was only assessing what it can do “if anything, to expedite the process” for the Covaxin application already under review at the World Health Organisation.

Sources also pointed out that the WHO’s processes don’t allow for “diplomatic” or “political” inputs, and are based entirely on the vaccine manufacturer’s ability to provide the documentation required by the international agency and to validate its claims. Bharat Biotech did not respond to The Hindu’s query on the planned meeting.

According to the WHO’s latest status report, published on May 18, Covaxin is one of 19 vaccines for which applications have been submitted. Seven

other applicants including vaccines made by Pfizer, Moderna, Johnson & Johnson's 'Janssen' vaccine, Chinese Sinopharm, and three versions of the Astra Zeneca vaccine, including Indian-made Covishield from the Serum Institute of India, have all received the green-light for the Emergency Use Listing (EUL).

The notification alongside the Covaxin application confirms that the application, or Expression of Interest, was received on April 19 this year, but that "more information [is] required", and that a pre-submission meeting prior to the EUL assessment would be planned in "May-June 2021". According to sources, the WHO is awaiting Bharat Biotech's Phase-3 final analysis data.

Covaxin has not yet approached the European Medicines Agency (EMA), which has authorised four vaccines including Moderna, Astra Zeneca and Janssen, and has another four under review.

The double recognition will help scientific research and collaboration between the Indian and foreign vaccine producers as well as help citizens to travel smoothly. Bharat Biotech has signed agreements with pharmaceutical companies from Brazil and the U.S. where the vaccine will be either co-produced or exported but the absence of endorsement from WHO and other multilateral bodies is creating difficulties for the vaccine.

At present Covaxin has been approved for use in nine countries — Iran, Philippines, Mauritius, Mexico, Nepal, Guyana, Paraguay, Zimbabwe and India.

India has used both Covishield and Covaxin for its "Vaccine Maitri" export programme. According to clinical trials conducted by Bharat Biotech, Covaxin has claimed interim clinical efficacy of 81% in dealing with the original COVID-19 and the mutant variants and the Indian diplomats are expected to take up these arguments when helping the company make its case with international agencies.

<https://www.thehindu.com/news/national/india-to-push-for-covaxin-recognition-by-who-and-eu/article34625955.ece>

Preshant Bhusan
(TRUE COPY)

ANNEXURE: A4

The Quint

Explained: Is the Data From Covaxin Trial's Bhopal Site Tainted?
Q&A on how Covaxin's Bhopal trial was to be conducted and why the data from the site isn't kosher.

PRIYANKA PULLA

Updated: 09 Feb 2021, 8:12 PM IST

COVID-19

Covaxin: The Q&A explains how the Bhopal trial was supposed to be conducted, how it was actually conducted, and why the data from the site isn't kosher.

In January 2021, several media outlets carried reports of worrying ethical breaches at People's Hospital – the Bhopal site of Bharat Biotech's phase 3 trial for Covaxin. The claimed breaches ranged from luring participants (by not clearly telling them they were part of a clinical trial, and not a vaccination drive) to not treating the participants when they fell sick during the course of the trial.

Now, a copy of the protocol of the Covaxin phase 3 trial, which The Quint has reviewed, shows that People's Hospital also violated this protocol, tainting the integrity of data from the site. Several experts The Quint spoke to said such protocol violations, together with already documented violations of the New Drug and Clinical Trial Rules 2019 (NDCT 2019), render the data from the site untrustworthy. This, in turn, will impact Bharat Biotech's calculations of the efficacy and safety of Covaxin from all of the 26 trial sites at the end of the study.

Both Bharat Biotech and the Indian Council of Medical Research (ICMR), the two sponsors of the trial, have brushed off the allegations. In responses *The Quint*, both said that People's Hospital had followed NDCT 2019 to the letter. In a response to this reporter, Director General, ICMR, Balram Bhargava, said:

"All due procedures laid down by DCGI (Drug Controller General of India) for obtaining informed consent, audio-visual recording, reporting AEFIs (adverse events following immunisation) etc have been followed stringently. There has been no violation in conduct of the trial as per the new clinical trial rules of DCGI."

This reporter also reached out to Bharat Biotech for a response. In a detailed mail, they denied any violation and said they strictly followed the NDCT 2019 rules on informed consent, recording of SAE and in investigating the death of the participant.

Neither of them explained some of the most egregious breaches reported in the media, such as the People's Hospital not giving copies of informed consent forms to every participant – a requirement under the NDCT 2019.

Bharat Biotech's and ICMR's responses are troubling because, by claiming there were no violations at all, they are implying that they plan to use data from People's Hospital as-is in the calculation of the vaccine's efficacy and safety.

The Q&A below explains how the Bhopal trial was supposed to be conducted, how it was actually conducted, and why the data from the site isn't kosher.

Bharat Biotech's phase 3 trial for Covaxin has two key goals – to characterise the efficacy and safety of the vaccine. Broadly, the team conducting the trial will calculate the efficacy by comparing the number of participants who develop Covid disease in the vaccine arm to the number in the placebo arm. Alongside, they will assess the vaccine's safety by comparing the rates of adverse events in both arms, and evaluating whether the vaccine caused some of the events (read about how investigators determine causality [here](#)).

According to the protocol accessed by The Quint, Bharat Biotech plans to assess Covaxin's safety on seven counts. These include the rates of solicited adverse events, unsolicited adverse events, serious adverse events, and the occurrence of so-called Vaccine Associated Enhanced Respiratory Disease (VAERD).

Solicited adverse events mean that the trial team is "soliciting", or asking each trial participant about expected side-effects within seven days of each injection. According to the protocol, the team was supposed to solicit twelve such events. The first four were pain, swelling, hardness (induration) and redness (erythema) at the injection site. In addition, the team was also supposed to look for fever, chills, headache, vomiting, nausea, muscle pain (myalgia) and joint pain (arthralgia).

“Serious adverse events” are when a participant dies or is hospitalised following a shot. And VAERD is when a vaccinated person develops a more severe version of COVID instead of being protected from it. A respiratory syncytial virus vaccine for babies, developed in the sixties, was seen to trigger this phenomenon. Because VAERD is a risk with Covaxin too, the phase 3 trial will be on the lookout for it.

The trial team at People’s Hospital was supposed to track this range of adverse events in several ways. For solicited adverse events, they were to telephone every participant for seven days after the first and second injections. In addition, each participant was given a daily diary to fill.

This data was to be collected in great detail, by grading each of the twelve solicited adverse events on a scale of 1 to 4. For instance, if a participant reported a fever of 39-40 degrees celsius, the team would record this as a grade 3 event. Or if a participant reported a red spot on the injection site that was between 50 mm and 100 mm wide, that would be a grade 2 event. The trial team was supposed to record such data for every one of the 1700 participants at People’s Hospital.

That isn’t all. Yet another crucial goal of the trial was to capture every single case of COVID-19 among participants throughout the one-year trial period. This data is central to both efficacy calculations and VAERD analysis. Again, this required People’s Hospital to follow-up participants rigorously, even aggressively. Through multiple channels, including SMS and phone, they were supposed to contact participants atleast once every

two weeks, to ask if they developed any COVID-19 symptoms. In addition, participants should have been able to contact a 24/7 helpline number.

Like with most vaccine trials, maintaining constant communication with all participants is emphasised in Bharat Biotech protocol. It is also clear from the protocol that every participant who fell sick during the trial, whether due to COVID or not, would be treated at the hospital.

Did People's Hospital follow this protocol scrupulously?

No, it didn't. If the participants are to be believed, the collection of data was extremely chaotic. Not only did the trial team fail to contact several participants at the pre-defined times, they also sometimes drove away participants who reported sick to the hospital. Both actions are the opposite of what the protocol demands.

Consider the claims of seventy-year old Man Singh Parihar, a construction worker, who joined the trial and received his first shot on 21 Dec. Parihar says that within two days, he became bedridden with fever, breathlessness and a headache.

If the People's Hospital team was playing by the rulebook, they would have called Parihar on the first seven days to collect solicited adverse events, and learnt that he was ill. His illness may have been classified as Grade 3 or 4, given that he was incapacitated, and requiring him to come to the hospital. Also, since his symptoms looked a lot like Covid, he would have been given an RT-PCR test. If he was diagnosed with COVID-19, the

data would be used for efficacy analysis and for VAERD assessment. If he wasn't, it would still go into the data sets for solicited adverse events.

But what actually happened was completely different: Parihar says nobody from the hospital called him in this time. Nor did he fill his diary, because he couldn't read or write.

Around the third day, his family took Parihar to a local medical practitioner, who gave him some drugs. But when he continued feeling ill until 7 January, 2021, Rachna Dhingra, a health activist who works with the victims of the 1984 Bhopal industrial-gas leak and their descendants (Parihar is one of them), told the family to call the principal investigator's number, listed in the diary.

Eventually, Parihar made his way to the hospital, a whole 16 days after he developed symptoms. This means the hospital lacks crucial data for over 2.5 weeks in his case.

Immediate recording of solicited adverse events is important, because people tend to forget the details beyond 24-hours, says Jacob John, an epidemiologist at the Christian Medical College, Vellore, and a part of the team that conducted the phase 3 trials for Rotavac, Bharat Biotech's rotavirus vaccine. "Usually, trial protocols are set up for a 24-hour recall of events," he says.

Several ongoing COVID vaccine trials have similar reporting systems for solicited adverse events. For example, the Phase 2/3 trial protocol for a Pfizer vaccine asks participants to note these events in an electronic diary

during the 7-day period following the shot. Trial teams are also required to review the diaries, preferably on a daily basis, and to call participants if they aren't filling them.

If People's Hospital lost data from only one participant, surely that isn't a big deal?

If it was only Man Singh Parihar who slipped through the trial's surveillance net, and the study team collected data scrupulously from the 1700+ other participants, the data would still largely be reliable.

But too many participants have described experiences similar to Parihar's, pointing to a badly-done trial and large chunks of missing data. While some, like Parihar, didn't get any of the seven phone calls (either after the first or second shot), others whom The Quint spoke to said they received only one or two.

Dhingra says she has identified 223 participants who experienced some protocol violation or the other, including not being tracked for solicited adverse events.

Another example that points to the chaos at People' Hospital is the experience of Jitendra Narvariya. This 36-year old daily wage-labourer received his first injection on 10 December. Four days later, he was coughing, feeling weak, and running a fever. Unlike Parihar, he did go to the hospital on the 14th of December. Here, he says, doctors told him to get a set of investigations done, for which he was asked to pay Rs 450. "Where was I to get the money? I am the only breadwinner in my family, and I was sick," he told The Quint. Narvariya earns Rs 400 a day.

Not knowing how he could afford the treatment, he went home. Eventually, on 5 January, 2021, nearly twenty days later (by when, Narvariya says, he still didn't get a single phone call), Dhingra convinced him to go back to the hospital. By then, reports of ethical breaches in the Bhopal trial had been widely covered in the media. People's Hospital then diagnosed him with a liver abscess, and hospitalised him for ten days.

In Narwariya's case too, the hospital has not only lost data, but also violated protocol by not offering him treatment when needed.

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So, the hospital didn't track solicited adverse events carefully. What about serious adverse events?

People's Hospital's investigation into the death of Deepak Marawi, a 45-year old participant, has raised troubling questions on this front too. Because serious adverse events lead to deaths or hospitalisation, investigators are obliged to probe any possible link with the vaccine. Even if a vaccine causes a slightly higher rate of such events, compared to a placebo, its risk-benefit ratio can change dramatically.

Yet, People's Hospital's conclusion that Marawi was poisoned, and that his death was unlikely to be due to the vaccine, has several flaws.

First, it ignores Marawi's family's account of his symptoms before his death. The family says Marawi's health deteriorated incrementally between December 12, when he got his first shot in the trial, and Dec 21, when he died. During this time, he experienced dizziness and weakness initially, followed by vomiting from December 17th onwards. Marawi's son, Aakash, also says that the hospital did not call his father between the 12th and the 21st (although the protocol requires seven calls in this period); nor did the investigators interview the family after the death to seek their version.

In contrast to what Marawi's family says, the dean of People's Medical College, A K Dixit, has claimed that the hospital called Marawi on all seven days, and that the latter had appeared to be fine.

The report of a post mortem analysis conducted at Bhopal's Gandhi Medical College only notes a sudden onset of anxiety, vomiting, and palpitations as Marawi's last symptoms, without specifying when they began.

These discrepancies between the family's claims and the hospital's are crucial to any analysis of what led to the demise, says Ajay Balachandran, a forensic pathologist at the Amrita Institute of Medical Sciences in Kochi. Yet, the hospital hasn't explained why it is not considering the family's account. Nor has it shared any evidence of the calls it made to Marawi, although the family has asked for it (Clinical trial sites typically maintain records of all attempts to contact participants).

Second, neither the post-mortem analysis, nor an analysis of viscera (internal organs) conducted after Marawi's death have identified the poison that triggered his symptoms. The results of the viscera analysis, conducted by the Regional Forensic Science Laboratory in Bhopal, and released on February 4th, only found ethyl alcohol and omeprazole, a drug used to treat acidity, in Marawi's stomach.

"Alcohol is a toxic substance, and people can die if they consume it in large quantities," Balachandran says. "But here, the symptoms are not consistent with alcohol poisoning."

Balachandran also cautions that the viscera report says nothing about the quantity of alcohol found. This is crucial because small quantities of alcohol can be formed in the body, even after death, due to natural processes. There are other flaws with Bharat Biotech's and People's Hospital's claims too. If the hospital knew for sure that Marawi had received a placebo, they could have let the vaccine off the hook. But the hospital has said that the trial investigators and ethics committee continue to be blinded; in other words, they didn't know whether Marawi got the vaccine or the placebo when they concluded that the vaccine wasn't linked his demise. All these discrepancies and unanswered questions suggest that People's Hospital did a hurried and superficial job of investigating Marawi's death.

When we reached out to Bharat Biotech for a response on SAE investigation, they said,

"This SAE has been thoroughly investigated and has been found not related to vaccine or placebo. All data and reports on this SAE has been submitted to the Site Ethics Committee, CDSCO and DSMB."

Why did People's Hospital find it so hard to follow the protocol?

It is hard to say. One possibility is that the investigators weren't trained in Good Clinical Practice (GCP), a set of standard practices aimed at ensuring data integrity and the protection of trial participants. NDCT 2019 requires all trial investigators to be trained and certified in GCP.

Several of People's Hospitals alleged actions point to a poor awareness of GCP. For instance, the vice chancellor of People's University, Rajesh Kapur, has admitted in an interview that the hospital gave a copy of informed consent forms to participants only when they asked for it. Sharing copies of the consent form is a requirement under both GCP and NDCT 2019.

The hospital also violated laws by recruiting vulnerable participants without the legally required checks and balances. According to NDCT-2019, when informed consent is sought from participants who are impoverished, or belong to ethnic minorities, the process must be recorded on video. The law also requires that an impartial witness be present when illiterate participants are consented. Yet, People's Medical College dean, Dixit has said in a press conference that the hospital wasn't doing either.

These provisions exist in NDCT-2019 to ensure that participants such as Parihar, Narwariya and Marawi aren't exploited. Apart from not being able to write, Parihar belonged to the Other Backward Class category of the

Madhya Pradesh government, while Marawi belonged to a Scheduled Tribe. In such cases, NDCT 2019, and the accompanying National Ethical Guidelines for Biomedical and Health Research Involving Human Participants recognise that the consent process may require investigators to make an extra effort. Video-recording helps document this effort.

But not only did People's Hospital skip the video-record, the informed consent process seems to have been rushed in several cases. Parihar and others have said they had no idea they were in a clinical trial, which is why it never struck them that they ought to report their symptoms to People's Hospital, and were entitled to medical care.

When The Quint asked A K Dixit whether the People's Hospital investigators had GCP certification, Dixit said the principal Investigator had received training from the company, but didn't answer a question about the remaining investigators.

How could the hospital have done things differently?

When it recruited so many vulnerable participants, the principal investigator and the ethics committee ought to have intensified their efforts to counsel participants and follow them up.

Dixit has said that upto 25% of the trial participants, or roughly 425 people, couldn't read or write. Dhingra estimates that the total number of vulnerable participants, as defined in the NDCT 2019, is close to 900. A consequence of this was that participants often did not have their own mobile phone, or shared it with several family members. This made the

two means of tracking solicited adverse events – telephone and a written diary, useless in many cases.

Such challenges in tracking vulnerable participants doesn't mean they should not be recruited, says Urmila Thatte, a clinical pharmacologist, bioethicist and Emeritus professor at the Seth GS Medical College and KEM Hospital, Mumbai. What it means is that extra care is taken to consent the participant, and to set up alternative channels of communication such as home visits.

“If a participant is not picking up the phone, you must find out why it isn't happening. One possibility is that the participant is too sick to answer. So, you have to use an alternate method – send a messenger home. As a caution, the investigators should have taken more than one phone number,” the investigator in another ongoing vaccine trial in India, who didn't wish to be named, told The Quint.

What should Bharat Biotech and ICMR be doing now?

A lot more than they have.

Bharat Biotech's trial in Bhopal was being overseen by multiple bodies, including the ethics committee, clinical trial monitor IQVIA, and an independent data and safety monitoring committee (DSMB). The job of each of these bodies was to respond immediately to allegations, and investigate them thoroughly.

But all these bodies have been silent in the matter.

Sahebrao K Sadawarte, a member of the ethics committee, refused to answer The Quint's questions, saying only that no violations had occurred. IQVIA India directed all questions from The Quint to Bharat Biotech. Meanwhile, the two sponsors of the trial, ICMR and Bharat Biotech, have denied any legal and ethical breaches.

This denial makes little sense in the face of how obvious some breaches are. It is also odd for ICMR to ignore them, because it is the author of the National Ethical Guidelines for Biomedical and Health Research and Human Participants, which Bharat Biotech and People's Hospital have violated. For instance, the National Ethical Guidelines contain the requirement that every participant be given a copy of the informed consent form. So, for ICMR to claim that there has been no breach, when People's Hospital's vice chancellor has admitted that this hasn't happened, is strange.

Given the lack of response from all bodies overseeing the trial, the Drug Controller General of India (DCGI), the agency tasked with enforcing NDCT-2019, ought to have stepped in. However, it isn't clear if DCGI has launched any investigation. Questions to the DCGI, V K Somani, from The Quint went unanswered.

If the ethics body had functioned as it was supposed to, it would have evaluated how widespread the breaches were. Several experts told The Quint that if they are indeed as extensive as claimed, data from the Bhopal site cannot be used in final calculations for either safety or efficacy. Thatte reasoned that any trial becomes invalid without informed consent.

“The participant is central to the trial. If they didn’t even know they were in a trial, that was wrong. Then all the data from the trial becomes invalid, to my mind.”

Urmila Thatte, Clinical pharmacologist, bioethicist and Emeritus professor at the Seth GS Medical College and KEM Hospital, Mumbai

Vasantha Muthuswamy, a bioethicist and a member of ICMR’s national ethics committee – which did not oversee the Bharat Biotech trial - agrees.

“If there are protocol violations, they must stop the trial at the site, and find a different site. The data cannot go into the analysis, because it will give the wrong results.”

Vasantha Muthuswamy, bioethics expert

A far bigger worry than the violations at People’s Hospital, however, is ICMR’s and Bharat Biotech’s blanket denial of them. Not only are these bodies overseeing the 25 other phase 3 trial sites, they are also collecting adverse event data from India’s Covid immunisation program, of which Covaxin is a critical part, points out Anant Bhan, a bioethics researcher at Mangaluru’s Yenepoya University. “To not acknowledge the problems, at all, is worrisome, because what does that tell us about how they handle potential concerns about data quality from other sites? If we are giving Covaxin on a large scale in clinical trial mode, and if this happens in a controlled trial, what about larger rollouts?” asks Bhan.

(Priyanka Pulla is freelance science journalist based in Bangalore. The reporting for this story was funded by The Thakur Family Foundation. The Foundation exercised no editorial control on the contents.)

ANNEXURE: A5

Live Mint

US students who took Covaxin, Sputnik V, asked to get re-vaccinated

Updated: 04 Jun 2021, 12:19 PM IST

Washington: Since March, over 400 US colleges and universities have announced students get Covid-19 vaccinations, ahead of the Autumn semester but those who have been inoculated with India's indigenous Covaxin or the Russian-made Sputnik V are being asked to re-vaccinate as these vaccines have not yet been approved by the World Health Organization (WHO).

Rukmini Callimachi reports in The New York Times that Milloni Doshi, a 25-year-old student from India, who is due to start her master's degree this fall at Columbia University's School of International and Public Affairs, has been administered two doses of Covaxin. Now, Columbia has told her that she will need to be revaccinated with a different vaccine once she arrives on campus.

"I am just concerned about taking two different vaccines. They said the application process would be the toughest part of the cycle, but it's really been all of this that has been uncertain and anxiety-inducing," Doshi wrote via a messaging app.

Campuses are proposing different measures, out of which the more complicated scenario is if students received a vaccine that has not been approved by the WHO, like Sputnik or Covaxin. Many colleges are proposing that those students will need to be revaccinated, which presents both medical and logistical conundrums.

This is primarily because no data exists on whether combining vaccines from different companies is safe. "Since Covid-19 vaccines are not interchangeable, the safety and effectiveness of receiving two different Covid-19 vaccines have not been studied," said Kristen Nordlund, spokesperson for the Centers for Disease Control and Prevention (CDC).

Nordlund also advised that people vaccinated outside the US with a vaccine not authorised by WHO should wait for a minimum of 28 days before taking the first dose of one of the Food and Drug Administration (FDA)-sanctioned vaccines.

American students have access to the Pfizer, Moderna and Johnson & Johnson vaccines, three of the eight doses authorised by the global health body. This disparity could hinder colleges that have made it a major priority to retain international students, who brought in close to USD 39 billion in tuition dollars in the year before the pandemic, according to an analysis.

"Universities want to enroll international students because they add diversity to the campus community -- and they bring money... It's why this has been a subject of intense discussion," said Terry W Hartle, senior vice president at the American Council on Education.

According to The New York Times, the situation is particularly challenging for students from India, which sends around 200,000 international students to American colleges every year. It is becoming increasingly hard to secure an appointment for a vaccine that will be accepted by American campuses.

"Every day, we get 10 to 15 messages and inquiries, saying 'What does this mean? How does this impact me?'" said Sudhanshu Kaushik, who runs

the North American Association of Indian Students, which is working to help fellow students.

Indiana University's vice president for international affairs, Hannah Buxbaum, said that the administrators of the institution are working overtime to answer the roughly 200 phone calls and 300 emails that are pouring in every day from the university's roughly 6,000 students overseas.

"Ringing off the hook doesn't begin to describe. There is no question that there is anxiety and concern among our international students," she said.

Many universities are only accepting the students who have been vaccinated with a WHO-approved COVID-19 vaccine. At Columbia, where one-third of the student body is from overseas, international students will be asked to present either their WHO booklet or a letter from a physician confirming they have received the requisite doses of one of the vaccines vetted by the world body, said Donna Lynne, the chief operating officer of the university's medical centre.

Callimachi writes for The New York Times that those who will not succeed in securing a vaccine before the start of the fall semester are facing a potentially problematic process.

Many universities were vague on how they plan to deal with the logistical complexity of spacing out these unrelated vaccines, beyond saying that they planned to accommodate students undergoing this process, reports The New York Times.

At least six regional governments in India have announced emergency clinics in the past week to vaccinate students going to US universities, in

wake of mounting pressure from confused and anxious students, wrote Callimachi.

However, Hyderabad-based Bharat Biotech on Thursday said that biopharmaceutical company Ocugen Inc will have exclusive co-development, manufacturing, and commercialisation rights of its COVID-19 vaccine Covaxin in Canada, in addition to its existing United States rights.

Preshant Bhusan

(TRUE COPY)

ANNEXURE: A6

Aljazeera

Which countries have stopped using AstraZeneca's COVID vaccine?

Concerns grow over reports of blood clotting among some recipients, but WHO urges countries to keep using the COVID vaccine.

15 Mar 2021

More than a dozen countries, mostly in Europe, have suspended the use of AstraZeneca's COVID-19 vaccine over fears the shot may have caused some recipients to develop blood clots.

Sweden and Latvia on Tuesday became the latest nations to halt the rollout, following moves by Germany, Italy, France, Spain, Denmark, Norway, and The Netherlands, among others.

Ireland temporarily suspends use of AstraZeneca vaccine WHO backs AstraZeneca coronavirus vaccine and plays down risks Bulgaria latest to halt AstraZeneca vaccine; WHO says no need AstraZeneca may miss second-quarter EU vaccine deliveries: Report

The World Health Organization (WHO) is meeting on Tuesday to review the available safety data on the vaccine, although it has repeatedly expressed confidence in its safety; WHO chief Tedros Adhanom Ghebreyesus has said there was no evidence of a link so far.

More than 17 million people have received the vaccine in the United Kingdom and the European Union to date, with fewer than 40 cases of blood clots reported as of last week, AstraZeneca, a British-Swedish multinational, said on Sunday.

The EMA reiterated its stance on Tuesday, that the vaccine is safe and its benefits outweigh any risks as coronavirus infections and deaths continue. The regulator will release results of its investigation into incidents of bleeding, blood clots and low platelet counts in recipients on Thursday.

But reassurances appear to have done little to calm doubts. These are the countries that have suspended use of the vaccine to date:

Sweden

Sweden's health agency on March 16 suspended the use of the AstraZeneca shot as a precautionary measure.

"The Swedish Public Health Agency has decided to suspend the use of AstraZeneca's covid-19 vaccine until the European Medicines Agency's investigation into suspected side effects is done," the agency said in a statement.

The Swedish Medical Products Agency said a day earlier it had recorded 10 cases of blood clots and one case of low levels of platelets among people who received the AstraZeneca vaccine, but not in combination.

Latvia

Latvian government health agencies on March 16 announced a "temporary suspension" of up to two weeks.

The move was taken as "an additional precaution" while the vaccine is scrutinised, and no problems have been linked to its use in Latvia, the agencies said in a statement.

France

President Emmanuel Macron on March 15 announced that France was suspending use of the AstraZeneca vaccine pending an EMA assessment of the shot.

"The decision has been made ... to suspend the use of the AstraZeneca vaccine as a precaution, hoping that we can resume it quickly if the judgement of the EMA allows it," Macron told a press conference.

Macron did not elaborate on the reasons for the decision but said he hoped France would be able to vaccinate with the AstraZeneca shots again "soon".

Germany

The German government on March 15 said it had halted use of AstraZeneca's shot.

The country's health ministry said the decision was taken as a "precaution" and on the advice of Germany's national vaccine regulator, the Paul Ehrlich Institute, which called for further investigation of the cases.

Italy

Italy's medicines agency on March 15 said it had joined other European nations in blocking the use of the AstraZeneca vaccine.

The move came just days after Italy's AIFA regulator banned the use of a single batch of the shot as a precaution while insisting there was no established link to the alleged side-effects.

"AIFA has decided to extend the ban on the use of AstraZeneca's COVID-19 vaccine throughout Italy as a precautionary and temporary measure pending European Medicines Agency (EMA) rulings," AIFA said in a statement.

Spain

Spain announced on March 15 that it would suspend use of the AstraZeneca vaccine for at least two weeks to allow experts to review its safety.

"We have decided to temporarily suspend [use of the AstraZeneca vaccine] as a precaution," Health Minister Carolina Darias told reporters.

Luxembourg

Luxembourg on March 15 said it was suspending use of the AstraZeneca shot as "a precautionary measure" until the EMA report on the vaccine is available.

Cyprus

Cyprus moved to pause use of the AstraZeneca COVID-19 shots on March 15 pending an EMA review of the vaccine.

The country's health ministry said the suspension will last until March 18, when the EMA is due to issue a review of the vaccine following reports of thrombosis among some recipients in Europe.

Portugal

Portugal temporarily suspended use of the AstraZeneca shot on March 15 following the reports of possible serious side effects.

Graca Freitas, head of the health authority DGS, told a news conference that although the side effects were "extremely severe", they were "extremely rare", adding no such cases had been reported in Portugal so far.

Officials said they hoped a scientific review of the jab can be completed by the end of the week.

Slovenia

Slovenia announced on March 15 that it was joining other European nations in suspending use of the AstraZeneca jab.

Health Minister Janez Poklukar said the government had taken the decision in order to "ensure the highest possible level" of safety.

"There is no medical expertise justifying this halt" but it is a preventive measure pending an opinion from the European Medicines Agency (EMA), he said.

Indonesia

Indonesia's health minister said on March 15 the country would delay administering AstraZeneca's COVID-19 vaccine.

"To be conservative, the food and drug agency delayed implementation of AstraZeneca [vaccine] as it awaits confirmation from the WHO," said Budi Gunadi Sadikin.

Indonesia received 1.1 million doses of the AstraZeneca vaccine via the global COVAX vaccine-sharing programme this month and is set to receive some 10 million more in the next two months.

The Netherlands

The Netherlands saw 10 cases of noteworthy adverse side effects, a Dutch drug watchdog said on March 15, hours after the government suspended the vaccine.

The Pharmacovigilance Centre Lareb said the reported incidents included cases of possible thrombosis or embolisms, but none included a lowered number of platelets, as has been reported in Denmark and Norway.

The vaccine will not be used until at least March 29 as a precaution.

Ireland

Ireland announced on March 14 that it had halted AstraZeneca "out of an abundance of caution" after reports from Norway of serious blood clotting in some recipients there.

Ireland's National Immunisation Advisory Committee (NIAC) recommended the suspension pending further information from the EMA.

"It may be nothing, we may be overreacting and I sincerely hope that in a week's time that we will have been accused of being overly-cautious," Deputy Chief Medical Officer Ronan Glynn said.

Bulgaria

Bulgaria on March 12 temporarily halted AstraZeneca after reports that a 57-year-old woman died hours after receiving a shot.

Prime Minister Boyko Borissov said the AstraZeneca rollout would be paused "until all doubts are dispelled and as long as the experts do not give guarantees that it does not pose a risk to the people".

The woman is believed to have died of heart failure; the autopsy found no blood clots.

The Democratic Republic of the Congo

The Democratic Republic of the Congo (DRC) announced on March 12 it was delaying the AstraZeneca vaccine, citing the European countries' moves.

The DRC received 1.7 million AstraZeneca doses via the COVAX scheme on March 2 but is yet to start its inoculation programme.

"We are going to check to know more about this problem," a spokesperson for the DRC's health ministry told Reuters news agency.

Thailand

Thailand was the first country outside Europe to delay the AstraZeneca vaccine, on March 12 – the day its political leaders were due to have the first shots.

The suspension was brief, however, and Prime Minister Prayuth Chan-ocha became the first person in Thailand to receive the vaccine on March 16.

AstraZeneca has said there is no evidence of an increased risk of blood clots in those individuals who have received the shot compared with those who have not [File: Luca Zennaro/EPA-EFE]

Romania

Romania temporarily stopped vaccinating people with one batch of AstraZeneca's COVID-19 vaccine – the same one in question in Italy – on March 11. Officials described the move as an "extreme precaution" until the EMA completes an inquiry.

Iceland

Iceland on March 11 suspended jabs with the vaccine as it awaited the results of an investigation by the EMA.

Denmark

Denmark on March 11 announced it was halting the use of the AstraZeneca shot for two weeks, following reports of blood clots in some people who had been vaccinated.

The Danish Medicines Agency later said a 60-year-old Danish woman who died of a blood clot after receiving the vaccine had "highly unusual" symptoms.

The woman had a low number of blood platelets and clots in small and large vessels, as well as bleeding, it said on March 14.

A few similar cases were found in Norway and in the EMA database of drug side effects, the Danish Medicines Agency added.

Norway

Norway also said it was suspending the use of the vaccine on March 11, as a caution amid the reports of possible serious side effects.

On March 13, Norwegian health authorities revealed that three health workers – all aged below 50 – who had recently received the AstraZeneca vaccine were being treated in hospital for bleeding, blood clots and a low blood platelet count.

“We do not know if the cases are linked to the vaccine,” said Sigurd Hortemo, a senior doctor at the Norwegian Medicines Agency.

The AstraZeneca shot is a ‘viral vector vaccine’, where a specially engineered virus that normally causes chimpanzees to get the common cold delivers genetic instructions to human cells to make the spike protein jutting out from the novel coronavirus’s surface [File: Jason Cairnduff/Reuters]

Austria

Before Denmark and Norway stopped their rollout, Austria on March 7 paused its use of a batch of AstraZeneca shots while investigating a death from coagulation disorders and an illness from a pulmonary embolism.

Estonia, Latvia, Lithuania and Luxembourg also suspended the use of the batch singled out by Austria.

Preshant Kushan

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सत्यमेव जयते

Ministry of Health & Family Welfare
Government of India

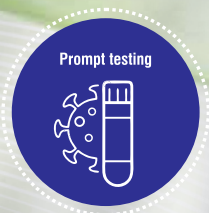
ANNEXURE: A7

72

COVID-19 VACCINES

OPERATIONAL GUIDELINES

(Updated as on 28 December 2020)



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2.3.1 DEVELOPMENT OF COVID-19 VACCINE

The Development of a vaccine is a time-consuming process that includes the following phases:

Table.2.1. Phases of vaccine development

Phases of vaccine development/trial	Purpose
Pre-clinical	Vaccine development in laboratory
Phase 1 Clinical trial (8-10 participants)	For testing vaccine safety
Phase 2 Clinical trial (50-100 participants)	For testing vaccine immunogenicity i.e. production of antibodies against virus
Phase 3 Clinical trial (30,000-50,000 participants)	For testing actual protection offered by the vaccine

The vaccine development process has been fast-tracked and multiple platforms are under development. Among those with the greatest potential for speed are DNA and RNA-based platforms, followed by those for developing recombinant-subunit vaccines. RNA and DNA vaccines can be made quickly because they require no culture or fermentation, instead use synthetic processes.¹¹

Per the tracker developed by the Vaccine Centre at the London School of Hygiene and Tropical Medicine, a total of 274 candidate vaccines are in different stages of development as of 4 December 2020, preclinical (215), phase I (25), phase I/II (17), phase II (5), phase II/III (1), phase III (10) and licensed (1).¹²

Table 2.2: Progress on COVID-19 Vaccine Development (Source: Vaccine Centre of London School of Hygiene and Tropical Medicine, accessed 4 December 2020).

Types of COVID-19 vaccines		Pre-clinical	Phase I	Phase I/II	Phase II	Phase II/III	Phase III	Licensed
Virus Vaccine	Live-attenuated	3	1					
	Inactivated virus	11	1	2	1		4	
Viral vector vaccine	Replicating viral vector	18	1	2	1			
	Non-replicating viral vector	26	6				4	
Nucleic acid vaccines	DNA vaccine	16	2	5				
	RNA vaccine	29	2	2	1		1	1
Protein based vaccine	Protein subunit	64	9	5	2		1	
	Virus like particle	17		1		1		
Unknown	–	31	3					
Total		215	25	17	5	1	10	1

With multiple COVID-19 vaccines under development, key characteristics regarding dosage, storage requirements, efficacy, route of administration, etc., currently remain unknown. However, a recent landscape document by WHO¹³ details 51 vaccines in clinical evaluation. The landscape document, as of 2 December 2020, indicates that most vaccines will require a two-dose schedule to be administered two, three or four weeks apart, and will be administered through-the intramuscular IM route.

11 Developing Covid-19 Vaccines at Pandemic Speed Nicole Lurie, M.D., M.S.P.H., Melanie Saville, M.D., Richard Hatchett, M.D., and Jane Halton, A.O., P.S.M.

12 https://vac-lshtm.shinyapps.io/ncov_vaccine_landscape/ accessed on 4 December 2020

13 <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>

FULL DETAILS (Read-only)

CTRI Number	CTRI/2020/11/028976 [Registered on: 09/11/2020] Trial Registered Prospectively	
Last Modified On:	17/03/2021	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Vaccine	
Study Design	Other	
Public Title of Study Modification(s)	A Phase 3, Randomized, Double-blind, Placebo-controlled, Multicenter Study to Evaluate the Efficacy, Safety, Immunogenicity, and Lot-to-Lot consistency of BBV152, a Whole virion Inactivated Vaccine in Adults greater than or equal to 18 Years of Age.	
Scientific Title of Study Modification(s)	An Event-Driven, Phase 3, Randomized, Double-blind, Placebo-controlled, Multicenter Study to Evaluate the Efficacy, Safety, Immunogenicity, and Lot-to-Lot consistency of BBV152, a Whole virion Inactivated SARS-CoV-2 Vaccine in Adults greater than or equal to 18 Years of Age.	
Secondary IDs if Any	Secondary ID	Registry
	BBIL/BBV152-C/2020 Version No: 3.0; Date: 20-10-2020	Protocol Number
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Name	Dr Krishna Mohan
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Source of Monetary or Material Support

Indian Council of Medical Research (ICMR), New Delhi

Primary Sponsor

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Address	Bharat Biotech International Ltd Genome Valley Shameerpet Hyderabad – 500 078 Telagana INDIA
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
The Indian Council of Medical Research ICMR New Delhi	Indian Council of Medical Research V. Ramalingaswami Bhawan, P.O. Box No. 4911 Ansari Nagar, New Delhi - 110029, India

Countries of Recruitment

India

Sites of Study Modification(s)

No of Sites = 26			
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		Jajapur	
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Dr Jitendra Singh Kushwaha	Prakhar Hospital	8/219 Khalasi Line Arya Nagar 3rd floor Kanpur Uttar Pradesh Kanpur Nagar	08448522450 dr.jskushwahacr@gmail.com
Dr Savita	Pt BD Sharma, PGIMS/UHS.	PGIMS Room no428 Department of Pharmacology	9812283746

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Details of Ethics Committee Modification(s)

No of Ethics Committees= 26	
Name of Committee	Approval Status
Ethics Committee of the Prakhar Hospital	Approved
Ethics Committee Sir Ganga Ram Hospital	Approved
Institutional Ethics Committe Aligarh Muslim University UP	Approved
Institutional Ethics Committe, Jeevan Rekha Hospital, belgaum	Approved
Institutional Ethics Committe, Maharaja Agrasen Superspeciality Hospital, Jaipur	Approved

Institutional Ethics Committee SRM College Hospital and Research Centre Tamil Nadu	Approved
Institutional Ethics Committee All India Institute of Medical Sciences Bihar	Approved 79
Institutional Ethics Committee All India Institute of Medical Sciences New Delhi	Approved
Institutional ethics committee DIRECTORATE OF PUBLIC HEALTH AND PREVENTIVE MEDICINE,Chennai	Approved
Institutional ethics committee Gmers Ahmedabad	Approved
Institutional Ethics Committee Grant Government Medical College and Sir J.J. Group of Hospitals Maharashtra	Approved
Institutional ethics committee ICMR-National Institute of Cholera and Enteric Diseases Kolkatta,West Bengal	Approved
Institutional Ethics Committee King George Hospital Visakhapatnam	Approved
Institutional Ethics Committee Lokmanya Tilak Municipal Medical College & General Hospital	Approved
Institutional Ethics Committee Mahatma Gandhi Medical College& Research Institute, Pondicherry	Approved
Institutional Ethics Committee Peoples university Bhopal, Madhya Pradesh	Approved
Institutional Ethics Committee Pt BD Sharma,PGIMS/UHS.Rohtak, Harvana	Approved
Institutional Ethics Committee Rahate Surgical Hospital & ICU Nagpur	Approved
Institutional Ethics Committee Redkar Hospital and Research Centre Oshalbag Village Dhargal, Tai- Pernem. Goa	Approved
Institutional Ethics Committee Vydehi Institute of Medical Sciences and Research Centre Bengaluru, Karnataka	Approved
Institutional Ethics Committee, Guntur Medical College, Government Fever Hospital, Government General Hospital, Gorantla, Guntur	Approved
Institutional Ethics Committee, IMS & SUM Hospital	Approved
NIMS Institutional Ethics Committee, Nizams institute of Medical Sciences, Punjagutta,	Approved
Prakash Medical college Institutional Ethics Committee	Approved
RCSMGMCIEC	Approved
Translational Health Science and Technology Institute (THSTI), ESIC Medical College and Hospital Faridabad	Approved

Regulatory Clearance Status from DCGI

Status

Approved/Obtained

Health Condition / Problems Studied

Health Type

Healthy Human Volunteers

Condition

Active immunization for the prevention of SARS-CoV-2 infection

Intervention / Comparator Agent

Type

Name

Details

Intervention

BBV152B: 6 µg antigen with Algel-IMDG

Whole-Virion Inactivated SARS-CoV-2 vaccine (BBV152) will be administered as a two dose intramuscular injection 28 days apart.

Comparator Agent

Placebo (Phosphate buffered saline with Algel)

Phosphate buffered saline with Alum (without antigen) will be used as the control.will be administered as a two dose intramuscular injection 28 days apart.

Inclusion Criteria	<table border="1"> <tr> <td data-bbox="322 92 443 165">Age From</td> <td data-bbox="454 92 2197 165">18.00 Year(s)</td> </tr> <tr> <td data-bbox="322 173 443 212">Age To</td> <td data-bbox="454 173 2197 212">99.00 Year(s)</td> </tr> <tr> <td data-bbox="322 220 443 258">Gender</td> <td data-bbox="454 220 2197 258">Both</td> </tr> <tr> <td data-bbox="322 266 443 619">Details</td> <td data-bbox="454 266 2197 619"> <p>1. Ability to provide written informed consent and availability to fulfill the study requirements. 2. Participants of either gender of aged 18 years and above. 3. Participants with good general health as determined by the discretion of the investigator, or participants with stable medical conditions. A stable medical condition is defined as a disease not requiring significant change in therapy or hospitalization or worsening disease during the 3 months before enrolment. 4. For a female participant of child-bearing potential, planning to avoid becoming pregnant (use of an effective method of contraception or abstinence) from the time of study enrolment until at least eight weeks after the last vaccination. 5. Male subjects of reproductive potential: Use of condoms to ensure effective contraception with the female partner and to refrain from sperm donation from first vaccination until at least 3 months after the last vaccination. 6. Agrees not to participate in another clinical trial at any time during the study period. 7. Agrees not to take any COVID-19 licensed vaccination for the entire duration of the study. 8. Agrees to remain in the study area for the entire duration of the study. 9. Willing to allow storage and future use of biological samples for future research.</p> </td> </tr> </table>	Age From	18.00 Year(s)	Age To	99.00 Year(s)	Gender	Both	Details	<p>1. Ability to provide written informed consent and availability to fulfill the study requirements. 2. Participants of either gender of aged 18 years and above. 3. Participants with good general health as determined by the discretion of the investigator, or participants with stable medical conditions. A stable medical condition is defined as a disease not requiring significant change in therapy or hospitalization or worsening disease during the 3 months before enrolment. 4. For a female participant of child-bearing potential, planning to avoid becoming pregnant (use of an effective method of contraception or abstinence) from the time of study enrolment until at least eight weeks after the last vaccination. 5. Male subjects of reproductive potential: Use of condoms to ensure effective contraception with the female partner and to refrain from sperm donation from first vaccination until at least 3 months after the last vaccination. 6. Agrees not to participate in another clinical trial at any time during the study period. 7. Agrees not to take any COVID-19 licensed vaccination for the entire duration of the study. 8. Agrees to remain in the study area for the entire duration of the study. 9. Willing to allow storage and future use of biological samples for future research.</p>
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Exclusion Criteria	<table border="1"> <tr> <td data-bbox="322 691 443 1137">Details</td> <td data-bbox="454 691 2197 1137"> <p>1. History of any other COVID-19 investigational or licensed vaccination. 2. Known history of SARS-CoV-2 infection, as declared by the subject. 3. For women, positive urine pregnancy test before the first dose of vaccination, or any time during the study period. 4. Temperature >38.0°C (100.4°F) or symptoms of an acute self-limited illness such as an upper respiratory infection or gastroenteritis within three days prior to each dose of vaccine. 5. Resident of COVID-19 infection in same household. 6. Known case of HIV, hepatitis B, or hepatitis C infection. 7. Receipt of any licensed/experimental vaccine within four weeks before enrolment in this study. 8. Receipt of immunoglobulin or other blood products within the three months before vaccination in this study. 9. Immunosuppression as a result of an underlying illness or treatment with immunosuppressive or cytotoxic drugs, or use of anticancer chemotherapy or radiation therapy within the preceding 36 months. 10. Immunoglobulins, anti-cytokine antibodies and blood products within 6 months prior to study vaccination, during and 21 days following last dose of vaccination. 11. Pregnancy, lactation, or willingness/intention to become pregnant during the first 6 months after enrolment. 12. Severe and/or uncontrolled cardiovascular disease, respiratory disease, gastrointestinal disease, liver disease, renal disease, endocrine disorder,, and neurological illness (mild/moderate well-controlled comorbidities are allowed) Re-Vaccination Exclusion Criteria 13. Pregnancy. 14. History of virologically (RT-PCR) confirmed SARS-CoV-2 infection 15. Anaphylactic reaction following administration of the investigational vaccine.</p> </td> </tr> </table>	Details	<p>1. History of any other COVID-19 investigational or licensed vaccination. 2. Known history of SARS-CoV-2 infection, as declared by the subject. 3. For women, positive urine pregnancy test before the first dose of vaccination, or any time during the study period. 4. Temperature >38.0°C (100.4°F) or symptoms of an acute self-limited illness such as an upper respiratory infection or gastroenteritis within three days prior to each dose of vaccine. 5. Resident of COVID-19 infection in same household. 6. Known case of HIV, hepatitis B, or hepatitis C infection. 7. Receipt of any licensed/experimental vaccine within four weeks before enrolment in this study. 8. Receipt of immunoglobulin or other blood products within the three months before vaccination in this study. 9. Immunosuppression as a result of an underlying illness or treatment with immunosuppressive or cytotoxic drugs, or use of anticancer chemotherapy or radiation therapy within the preceding 36 months. 10. Immunoglobulins, anti-cytokine antibodies and blood products within 6 months prior to study vaccination, during and 21 days following last dose of vaccination. 11. Pregnancy, lactation, or willingness/intention to become pregnant during the first 6 months after enrolment. 12. Severe and/or uncontrolled cardiovascular disease, respiratory disease, gastrointestinal disease, liver disease, renal disease, endocrine disorder,, and neurological illness (mild/moderate well-controlled comorbidities are allowed) Re-Vaccination Exclusion Criteria 13. Pregnancy. 14. History of virologically (RT-PCR) confirmed SARS-CoV-2 infection 15. Anaphylactic reaction following administration of the investigational vaccine.</p>						
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Method of Generating Random Sequence	Computer generated randomization								
Method of Concealment	Centralized								
Blinding/Masking	Participant, Investigator and Outcome Assessor Blinded								
Primary Outcome	<table border="1"> <tr> <td data-bbox="322 1520 2011 1552">Outcome</td> <td data-bbox="2022 1520 2197 1552">TimePoints</td> </tr> </table>	Outcome	TimePoints						
Outcome	TimePoints								

To evaluate the efficacy of BBV152B to prevent symptomatic COVID-19(Virologically confirmed-(RT-PCR positive) which include any participant who meets the Case Definitions for Symptomatic Endpoint and Severe Symptomatic COVID-19

Day 42 to Month 12

21

Secondary Outcome

Outcome	TimePoints
<p>EFFICACY:To evaluate the efficacy of BBV152B to prevent-</p> <ol style="list-style-type: none"> 1. COVID-19 based on the case definition for the secondary efficacy symptomatic endpoint. 2.COVID-19-Virologically confirmed (RT-PCR positive) severe cases of COVID19. 3.Any severity of COVID-19 by age. 4.Asymptomatic COVID-19. 5.COVID-19 regardless of symptomatology or severity 6.COVID-19 related deaths 7.Symptomatic COVID-19, regardless of the previous infection 	<ol style="list-style-type: none"> 1.Day 42 to Month 12 2.Day 42 to Month 12. 3.Day 42 to Month 12 4.Month 2 to Month 12 5.Day 42 to Month 12 6.Day 42 to Month 12 7.Day 42 to Month 12
<p>IMMUNOGENECITY To evaluate the immunogenicity of BBV152B</p> <ol style="list-style-type: none"> 1.Geometric Mean Titer (GMT) of SARS-CoV-2 Specific Neutralizing Antibody (nAb) 2.Geometric Mean Fold Rise (GMFR) of SARS-CoV-2 Neutralizing Antibody (nAb). 3.Geometric Mean Titer (GMT) of SARS-CoV-2 S1 protein-specific Binding Antibody (bAb). 4.Lot-to-Lot consistency will be assessed based on the neutralizing titer of the three consistent lots used in the trial 	<ol style="list-style-type: none"> 1.Month 0 to Month 12 2.Month 0 to Month 12 3.Month 0 to Month 12 4.Month 0 to Month 2
<p>SAFETY To assess the safety of BBV152B</p> <ol style="list-style-type: none"> 1.Serious Adverse Events occurring at any time 2.Solicited local and systemic adverse events (AEs). 3.Unsolicited AEs occurring between the vaccination and 28 days after the final vaccination. 4.Immediate AEs with 30 minutes of vaccination 5. Medically attended adverse events (MAAEs) or AEs leading to withdrawal 6.The occurrence of enhanced respiratory disease episodes reported by participant/documentated in hospital records 7.AE of Special interest 	<ol style="list-style-type: none"> 1.Throughout the study period 2.Within 7 days post each vaccination 3.Till 28 days post second dose vaccination 4. Within 30 minutes post each vaccination 5.Throughout the study period 6.Throughout the study period 7.Throughout the study period

Target Sample Size

Total Sample Size="25800"
Sample Size from India="25800"

Phase of Trial

Phase 3

Date of First Enrollment (India)

11/11/2020

Modification(s)

Date of First Enrollment (Global)

No Date Specified

Estimated Duration of Trial

Years="1"
Months="0"

Days="0"

Recruitment Status of Trial (Global) Modification(s)

Not Applicable

Recruitment Status of Trial (India)

Closed to Recruitment of Participants

Publication Details

NIL

This is a phase 3 Event Driven, randomized, double-blind, placebo controlled ,multicentre study to evaluate the Efficacy, Safety, and Immunogenicity of BBV152B, a Whole-Virion Inactivated SARS-CoV-2 Vaccine in Volunteers aged 18 years and above.

Protocol Version 1.0 to Version 2.0

- BBV-152B formulation is chosen based on the Phase 1 interim report which shows that the immunogenicity of BBV-152B is higher compared to BBV-152A although the difference was not statistically different.
- The primary efficacy endpoint is modified to include the participants who meet the case definition for Severe symptomatic COVID-19 .
- A safety endpoint to include the Adverse Events of Special Interest (AESIs) such as anaphylaxis, generalized convulsion, and vaccine associated enhanced respiratory disease (VAERD) is included.

Protocol Version 2.0 to version 3.0

- The case definition of symptomatic COVID-19 Endpoint is modified based on the SEC recommendation.
- Risks from study participation (Category 1 and Category 2 &3) is Updated for easy understanding for the participant

Brief Summary

A total of 25,800 subjects will be enrolled and randomized in a 1:1 ratio to receive BBV152B vaccine and control. All participants will be assessed for efficacy and safety endpoints and provide a NP swab and blood sample before the first dose of IP. The NP swab and blood collected will be subject to RT-PCR and Anti-SARS-CoV-2 IgG antibodies. The results of this will not affect enrollment of the participant. Participants who are found to be positive for either RT-PCR Or Anti-SARS-CoV-2 IgG antibodies will be excluded from the primary efficacy analysis. Safety follow up will be done for all. In addition, sites will be segregated based on the study objectives:

Category 1 (Symptomatic): In addition to administering the IP, a series of post-dose telephonic follow-up visits will be scheduled to detect suspect symptomatic COVID-19 infections. If a suspect is identified, a nasopharyngeal sample will be collected from the participant for detecting the presence of COVID-19 infection. Telephonic follow-up will occur at 15 Day intervals.

Category 2 (Symptomatic/Asymptomatic): In addition to administering the IP, a series of post-dose Nasopharyngeal samples for detecting incidence of asymptomatic COVID-19 infection at 1-Month intervals will be collected

Category 3 (Symptomatic/Asymptomatic+Immunogenicity): In addition to administering the IP and collecting NP samples, a series of blood samples will be collected for analyzing serum for immunological assessments.

The purpose of this Phase 3 study is to evaluate the protective efficacy, safety, and immunogenicity of the whole-virion inactivated SARS-CoV-2 vaccine, BBV152B. The Phase 3 study will follow randomized study participants for efficacy until virologically confirmed (RT-PCR positive) symptomatic COVID-19 participants will be eligible for the primary efficacy analysis. After reaching the target number (n=130) of symptomatic COVID-19 cases, the study will continue to assess safety until the completion of the study duration. It is planned to continue the Phase 3 trial until 130 study participants in the per-protocol population develop PCR-confirmed symptomatic COVID-19 disease during follow-up beginning 14 days after the second dose of vaccine or placebo. We estimate that approximately 25,800 participants should be randomized to accrue these 130 events. The Lot-to-Lot consistency (Immunogenicity) study will be nested within the Phase 3 (Efficacy) study (in three selected sites). The Immunogenicity study will assess the immune response of a 2-dose regimen of BBV152B vaccine through geometric mean titers (GMTs) by neutralizing antibody, S-protein, and RBD specific anti-IgG binding titer in a subset of 600 (450 vaccine: 150 control) participants, across three consecutive manufacturing Lots. Data generated through Day 56 (Month 2) will be unblinded only to the biostatistician for evaluation of immune responses in the Immunogenicity subset. A Formal interim analyses are planned when approximately 1/3 and 2/3 of the target number of participants with confirmed symptomatic COVID-19 have been accrued, to determine whether the sample size and/or length of follow-up should be increased. This interim report containing safety and immunogenicity data will be submitted to CDSCO.

Preshant Kushan

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सत्यमेव जयते

Select Language: English

Public Authorities Available

RTI Online

Version 2.0

An Initiative of Department of Personnel & Training, Government of India

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Online RTI Status Form

Note: Fields marked with * are Mandatory.

Enter Registration Number	MOHFW/R/T/21/01946
Name	Ramkumar
Date of filing	28/05/2021
Public Authority	Department of Health & Family Welfare
Status	REQUEST DISPOSED OF
Date of action	02/06/2021
<p>Reply :- Your queries: Through my RTI reference MOHFW/R/T/21/00987 dated 21-04-2021 , I got the reply from MOHFW on 04-05-2021 that vaccination is not Mandatory.</p> <p>With this</p> <p>1) Can any schools can deny the admission or deny to appear for exams if the student is not vaccinated ?</p> <p>2) Can any public or private sector can force their employees directly or indirectly for vaccination</p> <p>3) If any one of the student or employee expelled because of not vaccination , what is the way for them to get the justice ?</p> <p>Reply: Vaccination for COVID-19 is voluntary.</p> <p>However, it is advisable to receive the complete schedule of COVID-19 vaccine for protecting oneself against this disease and also to limit the spread of this disease to the close contacts including family members, friends, relatives and co-workers.</p> <p>Vaccination for COVID-19 is voluntary, therefore, no one can be deprived of any kind of Government service/facility/schemes due to non taking COVID vaccination.</p> <p>From 1st May 2021 onward all individuals above the age of 18 years are eligible for COVID vaccination.</p>	
CPIO Details :-	Satyendra Singh Phone: 011-23062959 singh.satyendra80@gov.in
First Appellate Authority Details :-	Sarita Nair Phone: 011-23061554 sarita.nair@gov.in
Nodal Officer Details :-	
Telephone Number	011-23061831
Email Id	r[dot]attri54[at]nic[dot]in

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Prashant Kushan

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ANNEXURE: P10**Zee News****No more mandatory negative COVID-19 RT-PCR report for train travel? Check what Indian Railways is planning*****Zee Media Bureau***

Updated: Jun 09, 2021, 14:45 PM IST

If you're planning to travel by train in the near future, then you might not have to carry the mandatory negative COVID-19 RT-PCR report.

As per sources, instead of a COVID-19 report, the Indian Railway is mulling to allow train passengers with a COVID-19 vaccination certificate. A person can also show his/her certificate through the Aarogya Setu app.

The move will also promote people to get vaccinated.

Sources claimed that this has been suggested to the Ministry of Railways by several states and the development can likely be confirmed by June 15.

Earlier on June 6, Minister of Civil Aviation (MoCA) Hardeep Singh Puri had also said that a joint team from several ministries and stakeholders, including the Health Department, are in discussion to take a final decision on allowing travelling by air without an RT-PCR test for those who have received both doses of a COVID-19 vaccine.

He had also stated that this decision will not be taken alone by the MoCA, nodal agencies, including health experts who are working with the government will also contribute towards making a decision in the

interests of passengers.

Currently, domestic passengers are mandatorily asked to produce a negative RT-PCR report before travelling to some states, where active COVID-19 cases are still high.

"Health is a state subject, and to ask passengers for a negative RT-PCR report before they enter a state is solely the right of that particular state," Puri added.

Meanwhile, India recorded 92,596 new COVID-19 cases and 2,219 deaths in the last 24 hours, the Union Health Ministry informed on Wednesday (June 9).

With this, the country's total coronavirus caseload has increased to 2,90,89,069, of which, 3,53,528 have succumbed to the virus, while 12,31,415 are active cases.

The cumulative number of COVID-19 vaccine doses administered across the country has also increased to 23,90,58,360.

Link: <https://zeenews.india.com/india/no-more-mandatory-negative-covid-19-rt-pcr-report-for-train-travel-check-what-indian-railways-is-planning-2367834.html>

Preshant Bhusan
(TRUE COPY)



UNION TERRITORY OF JAMMU AND KASHMIR
OFFICE OF THE DISTRICT DEVELOPMENT COMMISSIONER, KATHUA

Tel No. 01922-233258, Fax No. 01922-237626 Email: cdokathua2011@gmail.com

Subject:- Compulsory COVID-19 Vaccination by the Govt. Employees.

ORDER

Whereas, in order to control the spread of COVID-19, vaccination drives are under way in the district by the Health Department and;


Whereas, currently offices are functioning at reduced strength but they are expected to work with full strength as the COVID situation is improved. The Govt. employees of the district who have not get themselves vaccinated have to be compulsorily covered under the drive "vaccination of Govt. employees" and;

Whereas, the Govt. employees have more chances of getting infected with COVID-19 at the work place. A Govt. employee if got infected poses threat not only to its fellow colleagues but also to general public who visit Govt. offices in connection with their demands/grievances and;

Whereas, it is imperative to issue specific directions for the purpose.

As such, the following directions are hereby issued for strict adherence by all the concerned in letter & Spirit:

1. All the Govt. employees will get themselves compulsorily vaccinated before 30th June, 2021.
2. The concerned DDO will not draw the salary of the employees of his/her office unless they have get themselves vaccinated (except those who are contraindicative for the same).
3. A certificate will be recorded by the concerned DDO certifying that the salary bills of only those employees have been presented in the Treasury who have get themselves vaccinated.
4. The Treasury Officer will entertain the salary bills only after the above certificate of DDO is attached with the salary bills.
5. The Govt. employees will continue to follow covid-appropriate behaviour, even after vaccination, by maintaining hand hygiene, wearing face mask and observing social distancing etc.


Rahul Yadav, IAS
District Dev. Commissioner
Kathua

22/6

No: - DDCK/CPO/2020-21/Health/4745-4800

Dated: - 17.06.2020

Copy to the :-

1. Divisional Commissioner, Jammu for favour of information.
2. All District/Sectoral Officers for information & necessary action.
3. District Treasury Officer, Kathua/ All Treasury Officers for info. & necessary action.

ANNEXURE: A-12**INDIA TODAY****West Bengal: Covid vaccination certificates mandatory to enter parks but not hotels, malls**

According to West Bengal's latest Covid lockdown guidelines, it is mandatory to show a vaccination certificate to enter parks in the state. However, this is not the case for hotels and malls.

Prema Rajaram

Kolkata

June 15, 2021

UPDATED: June 15, 2021 22:25 IST

West Bengal [Chief Minister Mamata Banerjee on Monday extended the Covid lockdown](#) in the state till July 1. However, she announced some relaxations to the curbs.

One such relaxation is that parks have been permitted to open for three hours in the morning. However, those who want to enter will have to show proof of having taken two doses of the Covid-19 vaccine.

The government notification reads, "Parks may remain open for morning walks, physical exercise etc from 6 am to 9 am and only vaccinated people shall be allowed."

On the other hand, there is no such requirement to enter hotels, restaurants or malls which are likely to see bigger crowds as compared to parks. At hotels, restaurants and malls, owners will be responsible for ensuring their staff is vaccinated.

Morning walkers and joggers are concerned about the practicality of this new rule that requires them to furnish a vaccination certificate showing that they have taken both doses in order to enter parks.

"While this is a good decision as it ensures security of people in the park, it will take some time to practically implement this at the gates. Hence, there should be more volunteers to help the security personnel at the gates," said a

citizen who frequents the park surrounding Rabindra Sarovar lake in Southern Avenue.

Somendra Mohan Ghosh, who regularly goes for morning walks, said, "The parks are open only for three hours and it will take a long time to conduct checks. In many cases, the security guards themselves are not vaccinated. Someone can counter-question them about that. What happens then?"

While vaccination certificates carry the name of the person, there is no photograph. Hence, along with the certificate, people also have to carry their photo ID cards to enter the parks.

Under the new lockdown guidelines in the state, public transport including local trains, buses and autos will not ply till July 1. Gyms, swimming pools and sporting complexes will also remain closed.

Preshant Bhusan

(TRUE COPY)

भारत सरकार Government of India
 अंतरिक्ष विभाग Department of Space
 भारतीय अंतरिक्ष अनुसंधान संगठन Indian Space Research Organization
 सतीश धवन अंतरिक्ष केंद्र शार Satish Dhawan Space Centre SHAR

No.CON/2(2)/2021

June 06, 2021

CIRCULAR

Sub: Preventive and safeguarding measures against COVID-19 in SDSC SHAR- Reg.

Govt of India vide OMs No.11013/9/2014-Estt.A.III dated 06.04.2021 and No.11013/9/2014-Estt.A.III dated 03.05.2021 advised all the eligible employees to get vaccinated as a preventive measure to safeguard the employees and their family members. The same were endorsed by DoS and circulated to all employees by SDSC SHAR.

Accordingly, as a preventive and safeguarding measure, SDSC SHAR has organised various vaccination programs for all eligible employees, CISF personnel and their family members and facilitated for vaccination of employees of service providers of SDSC SHAR and Contractors.

In view of the above, as a preventive measure to safeguard the SHAR community and further contain the spread of COVID-19 it has been decided that:

1. Those employees who have completed 2 doses of vaccination, employees who have completed 14 days gestation period after 1st dose of vaccination and employees who were affected by COVID 19 within three month and fully recovered shall be allowed to attend for duties.
2. Employees who could not vaccinated due to medical reasons are directed to consult the physicians of SHAR and SDM Hospitals and produce the medical certificate for exemption of vaccination on medical grounds to the respective entity chiefs for further directions.
3. Those Employees who are not willing to get vaccinated are directed to produce COVID 19 RT-PCR negative report on every first working day of the week to the concerned Entity Chief for attending the duties.
4. Employees who are at outstation, are advised to get vaccinated at that place and inform the same to their divisional heads.

The above guidelines shall be in force with immediate effect and till further orders.

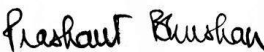
This is issued with the approval of the Competent Authority.


 (M Srinivasulu Reddy)
 Controller

To : All the employees of SDSC SHAR
 : All the Entity/Unit/Division/Section Heads

Copy to : Members of SAMC, SDSC SHAR
 : Chairman, Canteen Management Committee
 : DGM, TOMD, SDSC SHAR
 : Chief Medical Officer, SDSC SHAR
 : Head, Medical, SDMH
 : Sr. Commandant, CISF Unit, SDSC SHAR
 : Sr. Admn. Officer, PR, SDSC SHAR
 : General Secretary – SEA/SETU

CFI : Associate Director, SDSC SHAR
 : Director, SDSC SHAR



(TRUE COPY)

**BHARAT HEAVY ELECTRICALS LIMITED
TIRUCHIRAPPALLI - 620014**

BHE:No.:Covid 19:Vaccination

Date : 13.06.2021

CIRCULAR

Sub. : Covid – 19 Vaccination – Serving Employees – Reg.

The State Government of Tamilnadu vide G.O. dated 29.05.2021 directed that all employees working in Industrial Establishments have to vaccinate themselves within one month.

In order to comply with the above Government directives and for the benefit of our employees, a special vaccination drive was organized at Community Centre, BHEL Township and Factory Medical Centre (Unit I & II), in association with Trichy District Health Authorities. So far around **2900** employees in the age group of 18 years and above have got vaccinated. However, more than **50%** of the employees are yet to be vaccinated.

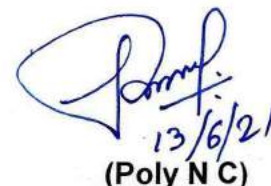
It is also learnt that a few employees have expressed their unwillingness to get vaccinated. In this regard, employees who are unwilling to take vaccination due to valid reasons, have to fill the attached format and submit the same to their respective Area HR Offices on or before **16.06.2021**.

In case of employees who have already got vaccinated on their own either at Govt. Primary Health Centre/Govt. Hospital or Private Hospitals are requested to update their vaccination details immediately in the online system (<https://trichy.bhel.com>). Employees shall use their **Employee Corner Password** to logon to the above system.

Appropriate action as deemed fit will be initiated against those employees who fail to get vaccinated on or before 28/06/2021 without valid reasons.

All are once again directed to get vaccinated themselves on or before **28.06.2021** without fail and protect yourselves, your family, co-employees and society at large from the infection/severity of Covid – 19.

This has the approval of Competent Authority



(Poly N C)

General Manager (HR, Medical & Civil)

Distribution :

All Employees through Maildesk
All General Secretaries of Participative Unions/EOU/BEAT
GMs/DROs

GM & Head (Trichy) – for kind information

Covid-19 Vaccination –Format for Unwillingness

Name :

Staff No. :

Designation :

Department :

/Through Controlling Officer/

I am aware that as per the Tamilnadu Government Order (G.O.) dated 29.05.2021, I am supposed to get vaccinated within one month.

However, at present, I am not willing to take vaccination for Covid – 19 due to one of the reasons given below **(Tick whichever is applicable)**:

1. I have been recently tested Positive and three months have not been completed from the date of discharge or home isolation.
2. I need to take RT-PCR test because one of my family member residing with me is currently tested Covid positive.
3. As of now, I have been advised by BHEL Company Doctor not to take vaccination due to medical reasons (Company Doctor Certificate attached).

Place :

Date :

Signature of Employee

Preshant Bhusan

(TRUE COPY)

**GOVERNMENT OF MEGHALAYA
OFFICE OF THE DEPUTY COMMISSIONER
WEST GARO HILLS::TURA::MEGHALAYA**

ORDER

Dated Tura, the 8th June, 2021

No. COVID-19/WGH/2020/205: - It has been brought to the knowledge of the undersigned that some of the Govt. employees of different offices of West Garo Hills District who are above 45 years of age have not been vaccinated till date. They are, therefore directed to get vaccinated or submit RTPCR Negative Test Report every 10 (ten) days with immediate effect to the concerned authorities. If, anyone is found Positive Case, they are directed to avail Earned Leave accordingly.

Therefore, all the heads of offices are hereby directed to prepare the list of employees and coordinate with District Immunization Officer to ensure 1st dose vaccination of all the employees who are above 45 years of age for ensuring health and safety of the co-employees of their respective offices, and the general public.

This order will also applicable for the office of the Sub-Divisional Officer, (Civil) and Block Development Officer(s), West Garo Hills District.



(Ram Singh, IAS),
Deputy Commissioner,
West Garo Hills Dist., Tura.

Dated Tura, the 8th June, 2021

Memo No. COVID-19/WGH/2020/205-A,

Copy for kind information and necessary action to:-

1. The Superintendent of Police, West Garo Hills, Tura.
2. ADC & CEO, DDMA, West Garo Hills, Tura.
3. The Sub-Divisional Officer, (Civil), Dadenggre/Raksamgre Civil Sub-Division.
4. All Branch Officer(s), O/o the Deputy Commissioner, Tura.
5. All Block Dev. Officer (s), West Garo Hills District.
6. All heads of Department, West Garo Hills District.
7. The District Immunization Officer, West Garo Hills District, Tura.



Deputy Commissioner,
West Garo Hills Dist., Tura.

Preshant Bhusan

(TRUE COPY)

**GOVERNMENT OF MEGHALAYA
OFFICE OF THE DEPUTY COMMISSIONER
EAST KHASI HILLS DISTRICT::SHILLONG**

No.C&S.2/CVD/2021/ORD/135

Dated Shillong, the 12th June, 2021.**ORDER**

In pursuance to Government Order vide No. POL.75/2020/Pt1/102, dated 11th June, 2021 and this Office Order No.C&S.3/2009/Pt.III/111 dated 11th June, 2021, the following arrangement is made for the week starting from 14th to 20th June, 2021 **in Shillong Urban Agglomeration:-**

- I. Identified shops dealing in essential commodities as notified by Incident Commanders under each Zone in **Shillong Urban Agglomeration** will open as per the following on the days mentioned below:-

Zone Wise Local Market Opening		
Name of the Zones/Blocks	Days of the Week on which the local markets in the Zones will be allowed to open	Timings
Zone – I (Laitumkhrah PS Areas)	Monday, Wednesday & Friday	9:00 AM to 3:00 PM
Zone – II (Laban PS Areas)	Monday, Wednesday & Friday	9:00 AM to 3:00 PM
Zone – III (Sadar PS Areas)	Monday, Wednesday & Friday	9:00 AM to 3:00 PM
Zone – III (Pasteur Beat House Areas)	Monday, Wednesday & Friday	9:00 AM to 3:00 PM
Zone – IV (Lumdingiri PS Areas)	Tuesday, Thursday & Saturday	9:00 AM to 3:00 PM
Zone – V (Rynjah PS Areas and Mawpat Block)	Monday, Wednesday & Friday	9:00 AM to 3:00 PM
Zone – VI (Madanring PS Areas)	Monday, Wednesday & Friday	9:00 AM to 3:00 PM
Zone – VII (Mawlai PS Areas and Mawlai Block)	Tuesday, Thursday & Saturday	9:00 AM to 3:00 PM
Mylliem C&RD Block	Tuesday, Thursday & Saturday	9:00 AM to 3:00 PM

- II. The following non-essential shops are permitted to open in a regulated manner. Applicants may apply to the concerned Incident Commanders or through the Local Headmen/CCMTs concerned and days for opening will be decided by the Incident Commander concerned:-

- | | |
|---|--|
| <ol style="list-style-type: none"> 1. Hardware stores and stores dealing in raw materials for construction. 2. Shops dealing in gas appliances and gas repairing. 3. Computer Store and peripherals. 4. Automobile showrooms for pending deliveries only and on specific request to this office. 5. Stationery, Xerox shops and Photography Studios. 6. Shops selling baby clothes. 7. Pet store & Pet feed. 8. Optical Stores. 9. Fabrication Units 10. Tailoring shops for pending orders only. | <ol style="list-style-type: none"> 11. Electrical and electronics shops. 12. Shops that sell, repair and service mobile phones and essential electronic items, and mobile phone recharging centres. 13. Automobile workshop and auto spare part shops. 14. Furniture Stores. 15. Furniture Workshops. 16. Agricultural tools and implements. 17. Printing press. 18. Florists and nurseries 19. Book Shops. 20. Garments and Shoe Shops only on need-basis and on specific request to the Incident Commander only. |
|---|--|

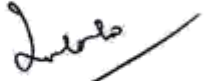
SHOPS NOTE:-

- a) Only Stand-Alone Shops are permitted to open and not Complexes/Malls.
- b) **All shops will place a prominent sign/poster indicating vaccination status of the staff/sales person.**
- c) Shops are encouraged to opt for home-delivery of items, **whenever possible.**



1. The Incident Commanders in consultation with the respective Headmen (Rangbah Shnong) and CCMTs of the respective zones will regulate opening of essential and non-essential shops in such a way as to ensure no crowding or congestion in and around the shop or market area.
2. The Headmen, Market Committee and CCMTs will be responsible for ensuring absolute adherence to protocols.
3. Everyone should wear double-masks (3-ply plus cloth mask) or N-95 mask without fail.
4. Social distancing of at least **2 metre** should be strictly maintained by all.
- 5. Tea shops are strictly prohibited from opening.**
6. People are not permitted to loiter in the market area without any valid reasons.
7. Anyone found violating protocols will be liable for **shop-closure** or **fined**.
8. There shall be no overcrowding in one area/shop and people should spend minimum time in the shop/market area.
9. **Anyone found moving and roaming around without essential reasons is liable to be punished as per law.**

Adequate stock is available and is being closely monitored by this office. Essential stores **will continue to open on a regulated fashion** notwithstanding any containment/lockdown order. Hence, there is no need to panic or rush to the markets.


 (Miss Isawanda Laloo, IAS)
 Deputy Commissioner,
 East Khasi Hills District,
 Shillong.

Memo. No.C&S.2/CVD/2021/ORD/135-A

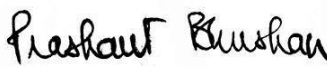
Dated Shillong, the 12th June, 2021.

Copy to:-

1. P.S to the Chief Secretary to the Government of Meghalaya for kind information of the Chief Secretary.
2. P.S to the Addl. Chief Secretary to the Government of Meghalaya, Home (Political) Department for kind information of the Addl. Chief Secretary
3. The Commissioner and Secretary to the Government of Meghalaya, Health & Family Welfare Department for kind information.
4. The Commissioner of Transport, Government of Meghalaya for kind information.
5. The Director, Food Civil Supplies & Consumer Affairs, Meghalaya for kind information and necessary action.
6. The Director of Information and Public Relations, Meghalaya for information and to cause wide publicity through local media and public announcement system.
7. The Superintendent of Police, East Khasi hills District for kind information and necessary action.
8. The SDO (Civil), Pynursla/ Sohra Civil Sub-Division for information and similar necessary action.
9. All Addl. Deputy Commissioner, East Khasi Hills District for kind information and necessary action.
10. The District Transport Officer, East Khasi Hills District for information and necessary action.
11. All Incident Commanders/Block Development Officers, East Khasi Hills District for information and necessary action.
12. All Headmen/CCMTs, East Khasi Hills District for information and necessary action.




 Deputy Commissioner
 East Khasi Hills District,
 Shillong


 (TRUE COPY)

Government of West Bengal
NABANNA
325, Sarat Chatterjee Road , Howrah -711102
ORDER

No 753-ISS/2M-22/2020

Dated:14 /06/2021

Whereas, in order to contain spread of COVID-19 pandemic, state government vide No 647-ISS/2M-22/2020 dated 15/05/2021 read with No 707-ISS/2M-22/2020 dated 29/05/2021 notified certain restriction measures in terms of the provisions under Disaster Management Act 2005 read with West Bengal Epidemic Disease, Covid-19 Regulations 2020 which are in effect upto 6PM of 15/06/2021.

Whereas, State Executive Committee of West Bengal State Disaster Management Authority on a review of the current situation of the pandemic and observing the likely positive impact of the containment measures in declining number of new cases, recommended further extension of restrictions with gradual and calibrated approach to relaxations.

Accordingly, in supersession of all earlier orders issued in terms of the provisions under Disaster Management Act 2005 read with West Bengal Epidemic Disease, Covid-19 Regulations 2020, **restriction measures stand extended upto 6PM of Wednesday 30th June 2021** with the following directives:

1. All schools/colleges / universities/ polytechnics/ Anganwadi centres and other educational/ academic institutions shall continue to remain closed.
2. All intra- state local trains, metro railway and intra- state bus services and inland water transport shall remain closed except for staff special trains for movement of emergency and essential services personnel.
3. Movement of private vehicles, taxis and auto-rickshaws will be prohibited except to and from hospitals, nursing homes, diagnostic centers, clinics, airports, terminal points, media houses etc.
4. All social / cultural/ academic/ entertainment related gatherings, groupings and congregations shall continue to be prohibited.
5. All beauty parlours, cinema halls, gyms, spa and swimming pools shall remain closed.
6. Not more than 50 persons shall be allowed at a time in marriage and other social gatherings.
7. Funeral rituals shall be allowed with not more than 20 persons at a time.
8. Government offices relating to emergency and essential services like health care, veterinary services, law and order, courts, social welfare homes, correctional services, power, drinking water supply, telecom, internet, print and electronic media, fire services, disaster management & civil defense, sanitation, sewerage and funeral services shall remain open as usual.
9. All Government offices other than as mentioned in para (8) will remain open as per normal working hours with 25 % of strength. Head of the Departments shall prepare a duty roster and facilitate transport arrangements for officials as required.
10. Private and corporate offices may remain open for restricted hours during **10 AM- 4 PM** with not more than **25 %** of the total strength. Employers shall make transport arrangements from their end and obtain e-passes from Kolkata Police/ District Administration.

11. All production units and industries including IT&ITES sector may function with **50%** of total strength in each shift subject to vaccination of employees, wearing of masks and maintenance of physical distancing. Employers shall make transport arrangements from their end and obtain e-passes from Kolkata Police / District Administration.
12. Parks may remain open for morning walks, physical exercise etc during **6AM to 9AM** and only vaccinated people shall be allowed.
13. Shops & vendors, bazaars and huts relating to vegetables, fruits, groceries milk, bread, meat and eggs shall be allowed to remain open between **7 AM to 11 AM** only.
14. All shops other than mentioned in para (13) above may remain open during **11 AM to 6 PM**
15. Restaurants and bars including in hotels and shopping malls may remain open during **12 Noon to 8 PM** with 50 % seating capacity.
16. Retail shops in shopping malls and market complexes may remain open during **11 AM to 6 PM** with 25% workforce and restricted entry of people/ customers upto 30% at a time.
17. Operations relating to tea auctions may resume with **25%** of total strength.
18. Games and sports may resume in stadium and clubs with sports facilities but without spectators.
19. Indoor/ outdoor shooting and associated activities related to TV programmes and cinema may resume with not more than **50** persons per unit at a time, subject to vaccination, wearing of masks, maintenance of physical distancing and with own transport arrangements and e-passes from Kolkata Police/ District Administration.
20. E-commerce / home delivery of all commodities shall be allowed.
21. Banks and Financial institutions shall remain open for restricted hours between **10AM to 2PM** and for operations of ATMs.
22. Petrol pumps, LPG gas offices and distribution centres shall remain open.
23. Print, electronic media and social media, MSOs and Cable operators shall remain open.
24. SEBI regulated and notified market entities shall remain open.

Wearing of masks, maintenance of physical distancing and health & hygiene protocol must be followed at all times.

Employers/ management bodies / owners / supervisors of above mentioned work places shall be responsible for provisioning of all COVID safety measures including regular sanitization of work places, vaccination of employees and for compliance of stated directives and COVID appropriate norms. Employers shall make transport arrangements for their staff and employees from their own end. Work from home must be encouraged as far as possible and practical.

All outdoor activities including movement of people and vehicles shall be prohibited between 9 PM to 5 AM except for health services, law and order, essential commodities including agricultural produce and other emergency services.

District administration, police commissionerates and local authorities shall ensure strict compliance of the stated directives. Any violation of the aforesaid restriction measures will be liable to be proceeded against as per the provisions of Disaster Management Act, 2005 and under Indian Penal Code.


Chief Secretary

Preshant Bhusan


(TRUE COPY)

**GOVERNMENT OF MEGHALAYA
OFFICE OF THE DEPUTY COMMISSIONER, RI BHOI DISTRICT,
NONGPOH**

ORDER

In view of the surging cases and 43 deaths due to Covid-19 without vaccination in the District and it has come to the notice of the undersigned that many Government Officials and staff in the District have not been vaccinated, hence, for the safety of everyone in the office and for those field staff interacting with public especially, mother & children, I, Smt.R.M.Kurbah, IAS, Deputy Commissioner, Ri Bhoi District, Nongpoh do hereby issue the following instructions:-

1. All Officials & staff are to get themselves vaccinated. If not vaccinated, they are to produce RTPCR Testing Certificate every 10 days. The test to be borne by the staff concern.
2. All ASHA's/AWWs are to get themselves vaccinated. If not vaccinated, they are to produce RTPCR Testing Certificate every 10 days. The test to be borne by the staff concern.
3. All shopkeepers are allowed to open their shops only after vaccination.
4. All drivers are considered as Frontline Workers; hence, they are not allowed to ply without vaccination.
5. Teachers are to get themselves vaccinated as they are/will be in contact with the school children.


Deputy Commissioner
Ri Bhoi District, Nongpoh
Dated: Nongpoh the 8th June, 2021

Memo.No.DDMA.RB/173/2021/29-A

Copy to:

1. All Addl. Deputy Commissioners, Ri Bhoi District, Nongpoh for kind information & necessary action.
2. All District Heads of Offices, Ri Bhoi District, Nongpoh for kind information & necessary action.
 - (i) The Head Assistant of all the offices in the District to maintain a separate register for the purpose.
3. The Extra Assistant Commissioner, Ri Bhoi District, Nongpoh for kind information & necessary action. To cross check the register maintained by the Head Assistant and to take action on defaulting staff.
4. The Incident Commander/Block Development Officer Umsning/Umling/Bhoirymbong/Jirang C&RD Blocks for kind information & necessary action.
5. The District Immunization Officer, Ri Bhoi District, Nongpoh for kind information & necessary action.
6. The District Surveillance Officer, Ri Bhoi District, Nongpoh for kind information & necessary action.
7. All Zonal/Sector Magistrates, Ri Bhoi District, Nongpoh for kind information & necessary action.
8. The District Public Relations Officer, Ri Bhoi District, Nongpoh for kind information & necessary action.
9. The DIO, NIC, DC's Office to display this Notification in the District Website.

Rashmi Kurbah
(TRUE COPY)


Deputy Commissioner
Ri Bhoi District, Nongpoh

GOVERNMENT OF PUDUCHERRY
PUDUCHERRY STATE EXECUTIVE COMMITTEE
-000-

No.104/PSEC/COVID19/2021

Puducherry, dt.07/06/2021

ORDER

- Sub: PSEC -Containment of Resurgence of COVID 19 - Instructions - Issued.
- Ref: 1. The Order No.40-3/2020-DM-I(A) dated 23/03/2021, 29/04/2021 and 27/05/2021 of the Ministry of Home Affairs, Government of India.
2. The Order No. 104/PSEC/COVID19/ 2021 dated 12/04/2021, 20/04/2021, 21/04/2021, 26/04/2021, 27/04/2021, 03/05/2021, 08/05/2021, 09/05/2021, 19/05/2021, 23/05/2021 and 31/05/2021 of the State Executive Committee, Puducherry.
3. The DO. No.Z.28015/85/2021-DM Cell dated 25th April, 2021 of Ministry of Health and Family Welfare (MoHFW).

The MHA, Government of India has issued directions vide D.O. letter No. 40-3/2020-DM-I(A), dated 27th May, 2021, directing to ensure compliance to the containment measures for COVID-19 upto 30th June, 2021.

2. Govt. of Puducherry has issued lockdown orders to contain the spread of COVID-19 virus. The last such lockdown order/notification issued vide No.104/PSEC/COVID19/2021 dated 31/05/2021, is effective upto 7th June, 2021 (mid-night).

3. The number of fresh positive cases have come down and therefore it is necessary to extend the **LOCKDOWN** to break the chain of Covid-19 transmission but with certain additional relaxations. Accordingly, the following lockdown measures are issued under Disaster Management Act, 2005, with effect from the **7th June, 2021 (mid-night) to 14th June, 2021 (mid-night)** for strict compliance by all concerned.

1.	Corona Night Curfew	There shall be Corona Curfew from 10.00 pm till 5.00 am every day.
2.	LOCKDOWN	In addition to the aforesaid Corona Night Curfew, there shall be lockdown with effect from 7th June, 2021 (mid-night) to 14th June, 2021 (mid-night) . Prohibited Activities : All Parks, Gardens, Cinemas / Theaters / Multiplex, Auditorium, Museum, Entertainment venue, Libraries shall remain closed for Public on all days. Gathering and congregations in any form shall remain strictly prohibited. Social / political / sports / entertainment / academic / cultural / festival related and other gathering in both open and closed spaces shall remain strictly prohibited.

Permitted activities and terms and conditions thereof:

All activities are prohibited except the following activities. People shall stay at their homes and shall not come out except for the following permitted activities. Such movement for the permitted activities would be subject to verification of the identity and purpose by the enforcement agencies. The enforcement agencies should verify the identity and purpose of the movement on roads and action should be taken against violators.

1. (i) All essential services Offices / departments viz., Raj Nivas/ Assembly/ Council of Ministers/ Chief Secretariat, Health, Revenue and Disaster Management, Police, Home Guard, Fire services, Jails, District Administration, Elections, LAD/local bodies, Civil Supplies, Industries, Labour, Animal Husbandry, Electricity, PWD, Forests, Agriculture, Treasury, Welfare Departments, Transport, Finance, Fisheries and Rural Development of Government of Puducherry shall function. The Administrative Secretaries/HODs of the aforesaid permitted offices/departments are also advised to avoid calling the staff for duty which may not be essential for the maintenance of essential services/Covid related services. The other departments / offices shall remain closed but employees / staff of such closed Offices /departments too, when engaged for COVID Management duties, shall attend their duties. Further the Administrative Secretaries/HODs of the closed departments shall make vehicles of their offices/departments available for COVID related duties. All staff in all the departments / offices working for the collection of Government revenues shall however attend their duty and ensure recovery of Government dues.

(ii) All Administrative Secretaries/HODs shall ensure vaccination of all eligible staff under them. Health Department shall ensure 100% coverage under vaccination for staff in the Health facilities. The Health Department shall saturate under vaccination all eligible persons in the population at the earliest.

2. All shops / commercial / business establishments shall be opened from 9.00 AM to 5.00 PM without air conditioning facility by following COVID protocol. However the vegetable / fruit shops shall be functional from 5.00 AM till 5.00 PM.

3. All Private Offices shall function with 50% staff strength from 9.00 AM to 6.00 PM.

4. The shops at Big Market shall be permitted to resume functioning at their respective placed inside the Market after strictly following the COVID norms.

5. Only home delivery/take away from restaurants/eateries /fresh juice / teashop is permitted upto 5.00 PM. Food shall be served to the Guests in Hotels and Lodges in their rooms only and the Guests shall not be permitted to dine in the restaurants attached to Hotels and Lodges. As such the dine-in facility /on the spot drinking in Restaurants, Hotels, Mess, eateries, teashops and fresh juice shall not be permitted.

6. (i) Only retail liquor including Arrack vends shall be allowed from 9.00 AM to 5.00 PM. Opening of liquor shops will pose a serious challenge of crowd control. Given the fact that shops had been closed for long and neighbouring State is yet to open its liquor vends, there may be a surge of crowd of intrastate and interstate (at the borders). It is imperative to put in place rigorous safety norms of barricading entrances, increased enforcement, safety norms of hand hygiene, social distancing etc. The Excise Department in joint co-ordination with Police Department shall ensure strict enforcement of crowd regulation at the Liquor vends. In particular, adequate security shall be put in place in shops located at the borders for enforcing crowd control/regulation. Duty charts be drawn for crowd regulation. The Excise Department shall issue stern directions on the safety norms to be followed by the retail liquor vends with no compromise, whatsoever failing which the shops/vends will be made liable.

(ii) The Excise department shall also expeditiously issue instructions for door step delivery of liquor within U.T. of Puducherry only, in consonance with its Act and Rules, so as to reduce the footfalls to liquor shops.

7) Goods transport shall remain permitted. Private, Government public passenger transport (buses/auto/taxies) shall also be permitted to operate upto 5.00 PM on all days by following COVID SOPs. However vehicle for medical and emergency purposes, marriages, death of a key relative, interview /examinations will be allowed on all days and at any time and they shall carry proof will them for the purpose.

8) Registration of Automobiles and issuance of Driving License shall be done by the Transport Department by following the COVID protocol.

9) Documents Registration shall be carried by following the COVID protocol.

10) Beach Road shall be opened from early morning 5.00 A.M. to 9.00 A.M. for regular walkers in the beach on all days. The walkers at the beach shall compulsorily wear masks and maintain social distancing norms.

11) All religious places / places of worship shall be opened for public for Darshan only upto 5.00 PM. However, essential Poojas / Prarthanas / Rituals are permitted to be conducted only by the priests/employees of the respective religious place. There shall not be any congregation at the place of worship. The religious institutions shall strictly abide by the SOP prescribed by Ministry of Home Affairs and Ministry of Heal and Family Welfare . At no point shall there be any relaxation in adhering to the COVID safety protocols.

12) Marriage related gathering shall be permitted but with guests not exceeding 25.

13) Funeral/last rites are permitted with participants not exceeding 20.

14) Industrial establishments, manufacturing centres and construction activities are permitted under the following terms and conditions;

- (a) Factories, manufacturing units and construction activities that are operating must subscribe to following discipline.
 - (i). Before opening the industrial establishments, manufacturing centres and construction activities, the employees should go for COVID Rapid Antigen Test (RAT) and within 15 days, all the eligible employees should be vaccinated as per criteria. Failure to get vaccinated will closure of the entity.
 - (ii). To scan body temperature of labourers pre-entry and confirm to COVID appropriate behaviour of all concerned.
 - (iii). If a labourer/ worker found positive, other labourers who have come into active contact with him to be quarantined with pay.
 - (iv). In case of any worker found to be positive, unit to be closed until completely sanitised.
 - (v). Lunch and tea breaks to be staggered for avoiding crowding. No common eating places.
 - (vi). Common toilet facilities to be sanitised frequently.
 - (vii). If a worker is found positive he or she would be allowed medical leave and cannot be discontinued during this absence for this reason.

15) All agricultural operations.

16) Following essential services shall be permitted without any time restrictions:

- (i) POL Bunks, ATMs, Telecommunication, Internet services, Broadcasting and Cable services, Media, IT and IT enabled services, Water supply, Sanitation, Electricity supply, Cold storages and ware housing services, private security services, Law and order/emergency/municipal/fire/Courts as per orders of High Court.
- (ii) Dairy & Milk supply / booth, pharmacy, hospitals, medical labs, Pharmaceuticals, Opticians, medicines and medical equipments, distribution of news papers, ambulance and hearse vehicle services, medical and its allied activities shall be permitted.

17) All E-Commerce activities shall be permitted.

18) The aforesaid shops / commercial establishment shall be closed down if they are found violating this lockdown order/ restrictions or COVID-19 appropriate behavior is not observed in and around their premises.

NOTE

General Public are advised to buy provisions, vegetables and other items from the shops near their houses and not travel long distances for purchase of these items. Enforcement agencies/ Police shall prevent general public travelling long distances for purchase of essential commodities.

4. Regional Administrators may align local restrictions in the area under their jurisdiction in keeping with restrictions in neighboring states/districts for the sake of better COVID management.

5. There shall be strict enforcement of these measures by the enforcement agencies/ Police who shall periodically and randomly carry out verification of persons travelling on road by establishing nakas/ road barriers at suitable places. Police shall also ensure strict border control to prevent cross border movement due to different pattern of restrictions between UT of Puducherry and neighboring States. Extant guidelines/instructions of MoH&FW and MHA, New Delhi shall be strictly enforced in the containment zones. The Enforcement officers concerned shall step up the imposition of fine on the violators under law. The National directives for COVID-19 management as specified in Annexure - I shall be strictly followed throughout the UT of Puducherry.

6. (a) All shops owners and persons working in shops / commercial establishment / industries are directed to get themselves vaccinated within 15 days, failing which they will not be allowed to function.

(b) Violation of restrictions/lockdown orders/ norms for containment zones by a shop/ commercial establishment/ industry shall be fined to a maximum level as permissible under the laws applicable.

(c) Violation of the lockdown order by stepping out of the home without any valid reason/ without identity card shall be fined.

(d) Any person violating the aforesaid lockdown or the National Directives will be liable to be proceeded against as per provision of 51 to 60 of Disaster Management Act and section 188 of IPC and other legal provisions as warranted.

7. This order substitutes all other previous orders issued on the subject and comes to force with immediate effect.

8. This issues as per directions of the Government / Hon'ble Lieutenant Governor, Puducherry.



(ASHOK KUMAR, I.A.S.)
SECRETARY (R&R) /
MEMBER SECRETARY (SEC)

To

1. All Members of the State Executive Committee, Puducherry
2. All Commissioner-cum-Secretaries to Government, Puducherry
3. The Director General of Police, Puducherry.
4. The District Collector - Cum - Chairman, DDMA, Puducherry / Karaikal.
5. The Regional Administrator, Mahe / Yanam.
6. All Heads of Departments, Puducherry

Copy to :

1. The Hon'ble Chief Minister, Puducherry
2. The Chief Secretary to Govt., Puducherry
3. The Secretary to HLG, Puducherry.

ANNEXURE-I
NATIONAL DIRECTIVES FOR COVID-19 MANAGEMENT

1. **Face coverings:** Wearing of face cover is compulsory in public places; in workplaces; and during transport.
2. **Social distancing:** Individuals must maintain a minimum distance of 6 feet (2 gazkidoori) in public places.
Shops will ensure physical distancing among customers.
3. **Spitting in public places** will be punishable with fine, as may be prescribed by the State/ UT local authority in accordance with its laws, rules or regulations.

Additional directives for Work Places

4. **Work from Home (WfH):** As far as possible the practice of WfH should be followed.
5. **Staggering of work/ business hours** will be followed in offices, work places, shops, markets and industrial & commercial establishments.
6. **Screening & hygiene:** Provision for thermal scanning, hand wash or sanitizer will be made at all entry points and of hand wash or sanitizer at exit points and common areas.
7. **Frequent sanitization** of entire workplace, common facilities and all points which come into human contact e.g. door handles etc., will be ensured, including between shifts.
8. **Social distancing:** All persons in charge of work places will ensure adequate distance between workers and other staff.

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(TRUE COPY)

ANNEXURE: A20



दक्षिण रेलवे/Southern Railway

मंडल कार्यालय/Divisional Office
वाणिज्य शाखा/Commercial Branch
तिरुवनंतपुरम/Thiruvananthapuram-14
दिनांक/Date:08.04.21

Note

Sub: -Covid Vaccination of commercial staff above 45 age group reg

1. All commercial staff (CC,TC,ECRC,CCTC) of age above 45 shall take covid vaccination within the next 72 hrs.
2. From 12/04/21 onwards Supervisors shall permit staff for duty only on production of vaccination certificate.
3. Staff who has not taken vaccination till 11/04/21 shall go on their own leave till get vaccinated.

वरि.मंडल वाणिज्य प्रबंधक/तिरुवनंतपुरम
Sr.DCM/TVC

Preshant Bhusan

(TRUE COPY)

ANNEXURE: A21

**PRISM JOHNSON LIMITED
KARAIKAL**

NOTICE

16.06.2021

SUB : COVID- 19 Vaccination.

As per the instruction of Karaikal Collector and Factory Inspector all are advised to put the first dose of COVID vaccine on or before 21.06.2021. Those who have taken their vaccine kindly share the hard copy of the certificate to time office at the earliest since the same has to be submitted to the Office of Inspector of Factories.

Those who have not vaccinated will not be allowed to the entre the factory from 22.06.2021. As per the order of the Government.

Enclosures : The order of the Collector



**V. JUDE ANANDARAJ
MANAGER (HR & ADMIN)**

**CC: The Secretary,
H&R Johnson Thozhilalargal Nala Sangam.**

Preshant Bhusan

(TRUE COPY)



Porur, Chennai - 600 116
Phone : 091-44-2476 8027, 31-33
Fax : 091-44-2476 5995
www.sriramachandra.edu.in

Ref.No.SSS/Reopening College/2021

Dated: 17.06.2021

CIRCULAR

As per the Vice-Chancellor's Circular No.055/VC/2021 dated 16th June 2021 it is notified that the onsite education for the students of all Faculties of the University will resume **from 5th July 2021**. The onsite sessions shall be used for practical training, while theory teaching will continue online.

Accordingly, all the students are instructed to submit the following at the time of attending classes on 5th July 2021

FOR DAY SCHOLARS

- Vaccination Certificate
- If Vaccination Certificate is not submitted, RT-PCR Negative Certificate (with 72 hours validity) and an Undertaking (copy attached) to get vaccinated within a maximum period of one week are to be submitted.

FOR HOSTELLERS

- Vaccination Certificate is mandatory.

In addition to the above, all the students must adhere to the safety precautions like social distancing, wearing face masks and hand hygiene etc.

To

Students concerned

Copy to: All Deans/Principals/HODs


All Officers of the University

Vice-Chancellor for information

The Chief Warden (Hostel)

The Chief Security Officer

DEAN-STUDENTS


DEAN - STUDENTS
SRI RAMACHANDRA
INSTITUTE OF HIGHER EDUCATION AND RESEARCH
(Deemed to be University)
Porur, Chennai - 600 116.



SRI RAMACHANDRA

INSTITUTE OF HIGHER EDUCATION AND RESEARCH

(Category - I Deemed to be University) Porur, Chennai

FOR GETTING VACCINATION UNDERTAKING BY STUDENT

I, Mr./Ms.------(full name of student)

Unique Id ----- studying in-----

Year-----Program-----

hereby declare as follows:

1. I have received a copy of the instructions pertaining to attending onsite education from 5th July 2021 onwards at Sri Ramachandra Institute of Higher Education and Research, Porur, Chennai 600 116.
2. I declare and undertake that I shall follow the above said instructions/guidelines strictly and get vaccinated within a maximum period of one week.
3. I agree that the College/University authorities can initiate disciplinary action against me if I fail to adhere to the instructions/guidelines during my presence in the SRIHER (DU) Campus.
4. I understand clearly that if I contract any illness due to my negligence/non-observation of the instructions/guidelines, I shall be held personally liable for all consequences thereof.

Place :

Signature of the Student

Date :

Name (in Capital letters):

Mobile No:

Email Id : :

(PTO)

DECLARATION

I, Mr./Ms. _____ (father / mother / guardian) of _____ (Name of student) hereby declare that my son/daughter/ward signed the above undertaking in my presence. I declare that I have instructed my son/daughter/ward to strictly follow the instructions/guidelines (copy of which is attached hereto).

Place : _____ Signature of the Parent/Guardian

Date : _____ Name (in Capital letters):

Mobile No.

Email Id: _____ :

Preshant Kushan
(TRUE COPY)

ANNEXURE: A23**Business Today.****COVID-19: No salary without vaccination for govt employees in this UP district**

Wednesday, June 2, 2021 | 14:17 IST

With a view to encourage COVID-19 vaccination, the district administration in Uttar Pradesh's Firozabad has ordered that government employees will not receive their salaries if they are not vaccinated.

District Magistrate Chandra Vijay Singh issued an oral order of "no vaccination, no salary", Chief Development Officer (CDO) Charchit Gaur said.

District treasury officer and other departmental heads have been given directions to implement the order and asked to make a list and ensure vaccination, Gaur said.

As per the order, if an employee does not take COVID-19 vaccine, the department will initiate action and stop his/her salary for the month of May, he added.

Government employees who are not vaccinated are trying to get their jobs so that their salaries are not withheld, Gaur said.

The state reported 1,317 fresh COVID-19 cases and 179 fresh fatalities because of the infection on Tuesday. The active cases stood at 32,465.

Earlier on Monday, the state government extended the relaxations announced in coronavirus curfew to six more districts from June 1, allowing shops and markets outside the containment zones to open for five days a week.

The relaxations are applicable to a total of 61 districts from June 1, while 14 districts with an active COVID-19 caseload of over 600 have been kept outside the purview of the order.

Link: <https://www.businesstoday.in/current/economy-politics/covid-19-no-salary-without-vaccination-for-govt-employees-in-this-up-district/story/440634.html>

Preshant Bhusan

(TRUE COPY)

ANNEXURE: A24

Indian Express

In MP, those not vaccinated get tagged with skull mark, a warning

Iram Siddique

Bhopal

Updated: June 10, 2021 7:39:45 am

A NEWLY launched Covid vaccination drive in Madhya Pradesh's Niwari district has led to policemen conducting checks on roads and making those who have not been vaccinated wear posters with skull marks — and the message: "*Mujhse dur rahein, maine abhi corona ka tika nahilagwaya* (Stay away from me, I haven't got vaccinated for Covid)."

Those who are handed these posters, under the drive in the district's Prithvipur block, are asked to read the message out loud and take an oath that they would get vaccinated within two days. Those who have been vaccinated are given badges with colours of the national flag and the message: "*Mein sacchadeshbhakthoonkyunkimaine corona ka tika lagwayahai* (I am a true patriot because I have been vaccinated)."

Asked about such measures being taken at a time when states are facing a shortage of vaccines, Niwari SP Alok Kumar Singh said the instructions were to just hand out the sticker or poster and not make anyone wear it. "It is one of the many initiatives and is only symbolic with an intention to create awareness," Singh said.

"With a third wave being anticipated, various awareness drives are being carried out to dispel the fear of vaccination, which is the only solution against the virus," he said.

Sub Divisional Police Officer Santosh Pandey, who is in charge of the drive in Prithvipur block, said "no partiality is shown". "I am a local from the adjoining Panna district and in this region of Bundekhand it is understood that if

someone swears over something, they will definitely fulfill it. That is why people are being made to take an oath to vaccinate themselves," said Pandey. SP Singh and Pandey said the drive was launched to overcome vaccine hesitancy, especially in the villages.

Bordering UP, Niwari has so far recorded 3,673 Covid cases. During the second wave in April, nearly 80 policemen were down with Covid. Since May 20, the daily count has mostly been in single digits. The district has recorded 47 deaths so far, of which 35 have occurred since May. There are currently 48 active cases in Niwari.

However, the district's pace of vaccination is yet to pick up with only 4.2 per cent of its population in the 18-44 age group covered so far. So far, 36,344 people (about 60 per cent) from a population of 59,885 above 45 years old have received at least one dose of the vaccine. But the campaign has covered only 8,582 of the district's 2.03 lakh population in the 18-44 age group.

On June 9, only 257 people above 45 years of age and 895 more in the 18-44 age range were vaccinated in Niwari. State-wise, Madhya Pradesh has vaccinated 1.35 crore people from a population of 7.2 crore.

Niwari District Collector Ashish Bargav said the district, which is the smallest in the state and was carved out of Tikamgarh just over two years ago, was recording nearly 3,000 vaccinations per day in March. But the campaign was "badly hit" when the state machinery was diverted to tackle the second wave, he said.

"Now, we are focused on vaccination as a part of which shopkeepers will be vaccinated on priority, and they are being encouraged to get their customers to get vaccinated. We have increased the number of camps. Also, all ground staff have been tasked with getting people to vaccinate," said Bhargav.

According to Prithvipur SDPO Pandey, police have also held meetings with traditional healers asking them to encourage people to get vaccinated. And, with Madhya Pradesh aiming to start easing Covid curbs from June 15,

shopkeepers “are also being asked to encourage at least five of their customers to get vaccinated”, he said.

ReshuSoni, a local resident who was made to wear the badge with the skull mark Tuesday, said: “You feel bad about being stopped and made to wear the badge but there were many who were made to do it. It is part of something good.” Soni said he managed to get his first dose at a local Primary Health Centre on Wednesday.

Sonu Vishwakarma, another local resident who received a badge with the national flag’s colours for having got his first vaccine dose, said: “This way of honouring and boycotting is better than getting beaten by police.”

Link: <https://indianexpress.com/article/india/coronavirus-in-mp-those-not-vaccinated-get-tagged-with-skull-mark-a-warning-7351737/>

Preshant Bhusan

(TRUE COPY)



ANNEXURE: A25

CIRCULAR

Dear Staff:

Getting a COVID-19 vaccine is an important step to prevent getting sick with COVID-19 disease. We care about your health. You are requested to receive the vaccine because everyone has essential role in fighting this pandemic. Getting vaccinated now will help protect you and your family you care for and who are at risk for severe illness from COVID-19. This is also an opportunity for you to serve as a role model in our community. By getting vaccinated first, you can positively influence vaccination decisions of co-workers, students, friends, and family. We understand you may have questions about the vaccine. COVID-19 vaccines are being held to the same safety standards as all other vaccines. You may have some side effects, which are normal signs that your body is building protection. The most common side effects are pain at the injection site, fever, and chills. These side effects tend to be mild to moderate and go away on their own within 1-2 days. COVID-19 vaccines are an important tool to help stop the pandemic. After vaccination, everyone should continue to follow all the current guidance to protect themselves and others, including wearing a mask, staying at least 6 feet away from others, avoiding crowds, following faculty guidance on visitation and infection control, and cleaning hands often.

Thank you again for all you will keep our students and faculty members, staff safe and healthy. We want you to feel confident in your decision to get vaccinated. The management has taken as a policy matter to protect every one, Vaccination certificate is mandatory for your physical appearance in the institute.

Thank you for everything. Please keep yourself and your co-workers safe and healthy.

Sincerely,

R. Parbhakar
Rajesh parbhakar 11/5/2021

Preshant Bhusan

(TRUE COPY)

PARUL UNIVERSITY

R/Circular-583/2021-22

Office of the Registrar
May 18, 2021

CIRCULAR

Sub:- Barring attendance in online classes for students who have not registered for Covid-19 vaccination

Ref:- (i) No.R/Circular-576/ 2021-22 dated 1.5.2021
(ii) Orders of the President

All the students in the university were informed to register for getting vaccination against Covid vide ref.(i). Many of the students have complied with this direction. Those students, who fail to register for vaccination up to May 29, 2021, will not be allowed to attend online classes from May 31, 2021.

Shri. Jatin Vaidya, Principal, PPI is given the responsibility of identifying the students who have not registered for Covid Vaccination and inform the concerned teachers through their HOIs to not allow such students to attend online classes from May 31, 2021.


Registrar

To,

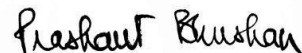
- 1) Shri. Jatin Vaidya, Principal, PPI
- 2) Principals/ Directors of Colleges/ Institutes

Copy to,

Campus Director

Submitted to,

- 1) The President
- 2) The Vice President
- 3) Dr.Parul Patel, Member, Governing Body and Chairperson, Admissions Committee
- 4) Dr. Geetika Madan Patel, Member, Governing Body and Medical Director
- 5) Dr.Komal Patel, Member, Governing Body and Director
- 6) The Provost



(TRUE COPY)

ANNEXURE: A27**Times of India****Max Life, Tata AIA Make Vaccination Must for Term Life**

Other insurers likely to follow suit; global reinsurers may have triggered the move

Ashwin.Manikandan @timesgroup.com

Mumbai: Max Life and Tata AIA have taken the lead in asking for mandatory Covid-19 vaccine certificates for buyers of term life insurance—opening the doors for other insurers to follow suit to reduce future claims payouts, but depriving cover to those who have not yet been inoculated.

While Max Life is issuing term covers to people over the age of 45 only if they are able to produce their final vaccination certificates, Tata AIA is issuing policies, irrespective of age, only to those who have received their first shot.

The trigger for these conditions for issuing new term policies seems to have originated from reinsurers such as Munich Re and Swiss Re, who are the biggest underwriters of risk for the domestic insurance companies.

Scrutinising policyholders on "To ensure the highest degree their vaccination status could of financial protection to our potentially solve two purposes policyholders, we ensure their for insurance companies interests are protected at all mes," a Tata AIA spokesperson said in reply to ET's emailed queries on the topic. "Our practices and policies reflect emerging realities. We continue to stay consumer-focused as well as prudent in our practices." Max Life didn't comment.

Preshant Bhusan
(TRUE COPY)

GOVERNMENT OF MEGHALAYA **ANNEXURE: A28**
OFFICE OF THE DISTRICT SCHOOL EDUCATION OFFICER:: WEST KHASI HILLS DISTRICT: 117
NONGSTOIN

No.DSEO/WKH/ COVID-19/583/2020/ 429

Dated Nongstoin, the 10th May. 2021

From:-

Smt. R. Kongwang,
District School Education Officer,
West Khasi Hills District, Nongstoin.

To, All the Principals/ Headmasters/ Headmistresses,
West Khasi Hills District.

Sub:- Mobilization for COVID-19 Vaccination.

Sir/Madam,

In view of the rapid increase in the spread of Covid.19 positive cases in the District, I am directed by the Deputy Commissioner, West Khasi Hills District, Nongstoin, vide letter No. COVID-19/MED-17/Pt.II/2021/8 dt. 8th May,2021 to instruct all the teachers both Private and Government institutions to get themselves vaccinated. Since teachers have to mix around with students and other teachers, they are vulnerable for the spread of the Covid.19 virus. Teachers are also required to assist the citizens who are 18+ age to register in the vaccination portal to enable them to get vaccination.

Teachers who fail to take the vaccination should undergo RTCPR test every 10 days and should submit report showing that they are negative (free from covid.19), failing which they should not be allowed to mix with the children in the schools and through contact tracing if they are found to be the carriers of Covid.19 they will be booked under the law.

This is for favour of your information and necessary action.

Yours faithfully,



District School Education Officer,
West Khasi Hills District, Nongstoin.
Dated Nongstoin, the 10th May. 2021.

(TRUE COPY)

Memo No DSEO/WKH/ COVID-19/583/2020/ 429 'A'

ANNEXURE: A29**Patrika News Network****Health department seeks report of vaccination of education department staff****If not vaccinated, then no salary**

Patrika News Network | patrika.com

Jabalpur. The situation regarding vaccination has not yet been clarified in the education department. Hence, the Health Department has called for a report on the status of vaccination in the Education Department. The Health Department has clearly said that if any employee teacher has not been vaccinated so far, then their salary for the coming month should be stopped. Unless a certificate of Covid-19 vaccination is presented by him after getting vaccinated, his salary should not be released. This instruction must be followed. The certificate will have to be checked - the department said.

It is that the head of the department concerned will have to verify the certificate given by the Government of India, and not verbal confirmation from his subordinate employees. It has to be seen whether the employee has taken the first and second doses. After taking the process of verification of vaccination certificate, the health department will also have to be informed in this regard.

A large number of staff are working in the education department. In this, there are more than 10,000 employees in the district, including principal, teacher, teacher, contract teacher, public teacher to clerk, babu, etc.

Preshant Bhusan

(TRUE COPY)

ANNEXURE: A30**NDTV****Delta Variant Predominant Despite Complete, Partial Vaccination: Study**

The study included 63 people who got breakthrough infections; of which 36 patients received two doses, while 27 had received one dose of vaccine.

All India Asian News International

Updated: June 10, 2021 2:27 am IST

The study has not been peer-reviewed yet (File)

New Delhi: A preliminary study conducted by the All India Institute of Medical Science (AIIMS), Delhi claimed that the presence of COVID-19 Delta variant (B.1.617.2) is predominantly found even after the first dose or both doses of vaccine has been administered.

The study included 63 people who got breakthrough infections; of which 36 patients received two doses, while 27 had received one dose of vaccine.

"SARS-CoV-2 lineages could be assigned for a total of 36 (57.1 per cent) samples, 19 (52.8 per cent) in patients who completed both doses and 17 (47.2 per cent) in patients who completed only a single dose. B.1.617.2 was found to be the predominant lineage with 23 samples (63.9 per cent) out of which 12 were in fully vaccinated and 11 in partially vaccinated groups. 4 (11.1 per cent) and 1 (2.8 per cent) samples were assigned the lineages B.1.617.1 and B.1.1.7 respectively. The B.1.617.2 lineage was first described in India and associated

with increased transmissibility as well as immune escape and has grown to become one of the predominant lineages in India," the AIIMS study said.

Ten patients received Covishield while 53 received Covaxin, of which 41 were males and 22 were females.

"Our analysis included 63 cases of vaccine breakthrough infections for which the dates of vaccines could be ascertained, of which 36 patients received two doses, while 27 had received one dose of vaccine. Ten patients received AZD1222/Covishield while 53 received BBV152/Covaxin," the study read.

The patients had a mean age of 37 (21-92), of which 41 were males and 22 were females. None of the patients had any comorbidities which could act as a predisposing factor for breakthrough infections.

"As lineage B.1.617.2 (Delta) was also prevalent in this group, any significant differences in lineages among fully and partially vaccinated samples were analysed. The difference was not found to be significant in both double dose vaccinated and single-dose vaccinated groups," the study added.

The report further stated that there are no reports of deaths in a sample size of 63 people, even though almost all cases reported high-grade unremitting fever for 5-7 days.

"Viral load at the time of diagnosis was high in all the patients irrespective of vaccination status or type of vaccine received. The initial course of disease with high-grade non-remitting fever lasted for five to seven days in the vaccinated group, similar to the clinical presentation in unvaccinated patients. During the subsequent course of illness, neither disease worsening (stable biomarkers) nor

mortality was reported in the present group, confirming the previous observations," as per the study.

The presence of Delta variant was about 60 per cent of people who received a double dose of either vaccine and it was found in 77 per cent of people who received one dose.

Of the breakthrough infection cases analysed, 10 patients (8 with double doses of vaccine and 2 with single vaccine dose) additionally had total Immunoglobulin G (IgG) antibodies assessed, of which 6 patients had IgG antibodies a month before the infection, while 4 had antibodies after the disease episode.

The patients included health care workers (24, 13 of which were from the same hospital) and close analysis of the genomic sequences suggests that the samples clustered separately with origins closely clustering with lineages from different states, suggesting the disease transmission happened most likely from different and independent sources.

The study also made the comment on the prevalence of Delta variant in Delhi and said, "Reinfections and vaccine breakthrough infections are rare occurrences and genomic sequencing of vaccine breakthrough infections can provide useful insights. In the present group of vaccine breakthrough infections investigated using genome sequencing, closely overlapping and mirroring the COVID-19 cases in the state of Delhi, the variants of concern B.1.617.2 and B.1.1.7 comprised the majority, but the proportions were not significantly different in comparison with

the population prevalence of the variants during this period with high community transmission."

Mortality due to COVID-19 was ascribed to 2 per cent cases (primarily older population, average age-82 years). The study has not been peer-reviewed yet.

(Except for the headline, this story has not been edited by NDTV staff and is published from a syndicated feed.)

Link: <https://www.ndtv.com/india-news/delta-covid-19-variant-found-to-be-predominant-despite-complete-partial-vaccination-aiims-study-2460339>

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ANNEXURE: A31**Hindustan Times News**

Home / India News /

'Indiscriminate vaccination can lead to rise of mutant strains': Experts tell PM

By hindustantimes.com | Written by Shankhyaneel Sarkar | Edited by Avik Roy, Hindustan Times, New Delhi

PUBLISHED ON JUN 10, 2021 10:44 PM IST

The experts highlighted the need of vaccinating people who are vulnerable and suffer from comorbidities. (HT File)

The study also highlighted that there is no need to vaccinate those who had been infected by Covid-19 previously and said that the vaccination of such individuals can be done after generating evidence that the vaccine is beneficial after natural infection.

A group of public health experts comprising doctors from All India Institute of Medical Sciences (Aiiims) and members from Covid-19 special taskforce on Thursday said that indiscriminate vaccination could lead to the rise of mutant strains, according to a news report by news agency PTI.

Uttar Pradesh vaccinates more than 5 million people in 18-45 age group

The study also highlighted that there is no need to vaccinate those who had been infected by Covid-19 previously and said that the vaccination of such individuals can be done after generating evidence that the vaccine is beneficial after natural infection. It also said that vaccinating the young population, given the current scenario, will not be cost-effective. The experts also recommended that local level sero-surveys in real time at the end of the second wave should be conducted repeatedly to map the vulnerability at the district level.

The Indian Public Health Association (IPHA), Indian Association of Preventive and Social Medicine (IAPSM) and Indian Association of Epidemiologists (IAE) also submitted the findings to Prime Minister Narendra Modi highlighting the need of vaccinating the people who are vulnerable.

India has administered 240 million Covid vaccine doses till now

“Mass, indiscriminate, and incomplete vaccination can also trigger emergence of mutant strains. Given the rapid transmission of infection in various parts of the country, it is unlikely that mass vaccination of all adults will catch up with the pace of natural infection among our young population,” the study said.

Committed to prevent misuse of data regarding Covid-19 vaccines, says Centre

“The present situation of the pandemic in the country demands that we should be guided by the logistics and epidemiological data to prioritise vaccination rather than opening vaccination for all age groups at this stage,” the study further added.

Allow walk-in Covid jabs, online registration not enough: Rahul Gandhi to Centre

“Vaccine is a strong and powerful weapon against the novel coronavirus. And like all strong weapons it should neither be withheld nor used indiscriminately; but should be employed strategically to derive maximum benefit in a cost-effective way,” the report further added.

The recommendation also include addition of 17 more laboratories to the Indian SARS-CoV-2 Genomics Consortium (INSACOG) and achieving the target of genomic sequencing of at 3% of the positive samples.

(with inputs from PTI)

Link:<https://www.hindustantimes.com/india-news/indiscriminate-vaccination-can-lead-to-rise-of-mutant-strains-experts-tell-pm-101623344820669.html>

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ANNEXURE: A32

NIH RESEARCH MATTERS

January 26, 2021

Lasting immunity found after recovery from COVID-19

At a Glance

The immune systems of more than 95% of people who recovered from COVID-19 had durable memories of the virus up to eight months after infection.

The results provide hope that people receiving SARS-CoV-2 vaccines will develop similar lasting immune memories after vaccination.

Colorized scanning electron micrograph of a cell, isolated from a patient sample, that is heavily infected with SARS-CoV-2 virus particles (red). NIAID Integrated Research Facility, Fort Detrick, Maryland

After people recover from infection with a virus, the immune system retains a memory of it. Immune cells and proteins that circulate in the body can recognize and kill the pathogen if it's encountered again, protecting against disease and reducing illness severity.

This long-term immune protection involves several components. Antibodies—proteins that circulate in the blood—recognize foreign substances like viruses and neutralize them. Different types of T cells help recognize and kill pathogens. B cells make new antibodies when the body needs them.

All of these immune-system components have been found in people who recover from SARS-CoV-2, the virus that causes COVID-19. But the details of this immune response and how long it lasts after infection have been unclear.

Scattered reports of reinfection with SARS-CoV-2 have raised concerns that the immune response to the virus might not be durable.

To better understand immune memory of SARS-CoV-2, researchers led by Drs. Daniela Weiskopf, Alessandro Sette, and Shane Crotty from the La Jolla Institute for Immunology analyzed immune cells and antibodies from almost 200 people who had been exposed to SARS-CoV-2 and recovered.

Time since infection ranged from six days after symptom onset to eight months later. More than 40 participants had been recovered for more than six months before the study began. About 50 people provided blood samples at more than one time after infection.

The research was funded in part by NIH's National Institute of Allergy and Infectious Diseases (NIAID) and National Cancer Institute (NCI). Results were published on January 6, 2021, in *Science*.

The researchers found durable immune responses in the majority of people studied. Antibodies against the spike protein of SARS-CoV-2, which the virus uses to get inside cells, were found in 98% of participants one month after symptom onset. As seen in previous studies, the number of antibodies ranged widely between individuals. But, promisingly, their levels remained fairly stable over time, declining only modestly at 6 to 8 months after infection.

Virus-specific B cells increased over time. People had more memory B cells six months after symptom onset than at one month afterwards. Although the

number of these cells appeared to reach a plateau after a few months, levels didn't decline over the period studied.

Levels of T cells for the virus also remained high after infection. Six months after symptom onset, 92% of participants had CD4+ T cells that recognized the virus. These cells help coordinate the immune response. About half the participants had CD8+ T cells, which kill cells that are infected by the virus.

As with antibodies, the numbers of different immune cell types varied substantially between individuals. Neither gender nor differences in disease severity could account for this variability. However, 95% of the people had at least 3 out of 5 immune-system components that could recognize SARS-CoV-2 up to 8 months after infection.

"Several months ago, our studies showed that natural infection induced a strong response, and this study now shows that the responses last," Weiskopf says. "We are hopeful that a similar pattern of responses lasting over time will also emerge for the vaccine-induced responses."

—by Sharon Reynolds

References: Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection. Dan JM, Mateus J, Kato Y, Hastie KM, Yu ED, Faliti CE, Grifoni A, Ramirez SI, Haupt S, Frazier A, Nakao C, Rayaprolu V, Rawlings SA, Peters B, Krammer F, Simon V, Saphire EO, Smith DM, Weiskopf D, Sette A, Crotty S. *Science*. 2021 Jan 6:eabf4063. doi: 10.1126/science.abf4063. Online ahead of print. PMID: 33408181.

Funding: NIH's National Institute of Allergy and Infectious Diseases (NIAID) and National Cancer Institute (NCI); La Jolla Institute for Immunology; John and Mary Tu Foundation; Bill and Melinda Gates Foundation; Mastercard; Wellcome; Emergent Ventures; Collaborative Influenza Vaccine Innovation Centers; JPB Foundation; Cohen Foundation; Open Philanthropy Project

Link: <https://www.nih.gov/news-events/nih-research-matters/lasting-immunity-found-after-recovery-covid-19>

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ANNEXURE: A33

The Wire Science

617 Serious Adverse Events After Vaccination Reported In India Until March 29

09/04/2021

THE WIRE STAFF

A medical worker holds a vial of AstraZeneca's COVID-19 vaccine at a vaccination centre in Ronquieres, Belgium, April 6, 2021. Photo: Reuters/Yves Herman/File Photo

Bengaluru: As of March 29, 2021, at least 617 serious adverse events following immunisation (AEFI) had been reported from around the country, according to a presentation made before the National AEFI Committee two days later. Of these 617, at least 180 people (29.2%) died, and of these, complete documents were available only for 35 people (19.4%).

According to vaccine scientist Dr Gagandeep Kang, there are five types of AEFIs: vaccine product related reaction, vaccine quality defect related reaction, immunisation error related reaction, immunisation anxiety related reaction and coincidental event. The National AEFI Committee is tasked with determining the type of each AEFI in the country and, where applicable, arranging for compensation for the affected parties and/or informing vaccine regulation.

The Government of India has been drawing flak for some time after it stopped publishing AEFI reports after February 26, around 40 days after the

start of India's COVID-19 vaccination drive, and after a seemingly laidback response to concerns about AstraZeneca's shot, called 'Covishield' in India.

According to the slides presented on March 31, prepared by the Immunisation Technical Support Unit at the health ministry and which The Wire Science has seen, the ministry has ascertained the type of AEFI for 492 reports. Of them, 63 people didn't require hospitalisation, 305 people required hospitalisation and 124 people died. A little more than half of those who died did so due to acute coronary syndrome, which refers to any conditions that suddenly and significantly reduce blood flow to the heart, including heart attacks.

However, according to the presentation, complete documents were available for only 35 people. These documents refer to case reporting forms and case investigation forms that the corresponding healthcare workers must file at the district level for each case.

"Currently, we are observing gaps in how serious adverse events are being investigated at the district level," Delhi-based public health researcher Malini Aisola had previously told IndiaSpend on March 9. "In some cases there is a post mortem, in some cases there isn't." She told The Hindu on April 9 that "in at least six out of 10 cases where the National AEFI Committee has completed causality assessment, no post mortem has been done".

On March 17, as The Wire Science reported, "the immunisation division of the health ministry released a note (Z.16025/02/2018-IMM) saying it had considered eight AEFIs. A subcommittee had determined four were

“coincidental”, one was “unclassifiable” and three were designated B1: “reviewing factors result in conflicting trends of consistency and inconsistency with causal association to immunisation.” All of these cases were among recipients of Covishield.

Dr Jacob John, formerly of Christian Medical College, Vellore, also pointed to a preliminary pattern in the data – that the incidence of deaths wouldn’t be bunched together in time, and might be more evenly distributed, if they were all coincidental. As Prasad Ravindranath, the article’s author, notes, “there are 93 deaths in the first three days and 18 deaths in four-seven days after vaccination. There have been 11 deaths in 8-28 days post-vaccination.” This and similar patterns merit further investigation, according to Dr John.

The presentation doesn’t mention the name of the vaccine for each of the AEFI events, but since last month, there have been widespread concerns in Europe that the AstraZeneca shot may be associated with rare but debilitating blood clots. While authorities in Europe insisted that the shot’s benefits outweighed its risks and that people should continue receiving it, some governments as well as an assessment body of the European Medicines Agency (EMA) said there could be a very small risk factor for cerebral venous sinus thrombosis.

According to The Hindu, the EMA “included only six deaths from India after vaccination with Covishield for its analysis” because, Aisola said, of “a massive backlog in processing assessments in India”. In addition, Dr Kang also said in an interview with Karan Thapar for The Wire last week that while

the risk is low, the issue has been compounded by the Indian government's secretive deliberations on the matter.

Link: <https://science.thewire.in/health/617-serious-adverse-events-after-vaccination-reported-in-india-until-march-29/>

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VAERS COVID Vaccine Data

(Vaccine Adverse Events Reporting System, USA)

358,379 Reports
Through June 11, 2021

*

[jump to browse highlighted reports](#) ▾

5,993

DEATHS

20,737

HOSPITALIZATIONS

47,837

Urgent Care

65,623

OFFICE VISITS

1,538

1,868
BELL'S PALSY

6,157
Life Threatening

2,323
Heart Attacks

1,342
Myocarditis/Pericarditis

1,671
Thrombocytopenia/Low Platelet

692
Miscarriages

16,275
Severe Allergic Reaction

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ANNEXURE: A35

THURSDAY, JUNE 24TH, 2021|

The Daily Expose

How can the UK Gov. make these mandatory? – 20th update on Adverse Reactions to the Covid Vaccines shows 949,287 Adverse Reactions & 1,332 Deaths

BY THE DAILY EXPOSE ON JUNE 19, 2021 • (24 COMMENTS)

The UK Government / MHRA have released their 20th update on adverse reactions to the Covid-19 vaccines just days after announcing new legislation is to be brought in that will make it mandatory for anyone working in a care home to have two doses of a Covid-19 vaccine unless they have a medical exemption.

But this does not just include carers. The legislation is also being extended to require anybody who comes into the care home to do other work, such as tradespeople, and hairdressers and beauticians. Can you see where this is going? If this law comes to pass it will not be long before you will be required to be fully vaccinated so you are able to visit your family member in their care home.

After this they may decide hairdressers entering care homes who have clients outside of care homes are still a danger to those in care homes if their other customers are not vaccinated. Therefore, it will become a requirement to have two doses of one of the Covid vaccines to use a hairdressers.

Make no mistake, mandatory vaccinations will not start and end at care home workers.

But we must ask how on earth it is possible to make unlicensed, experimental treatments mandatory? Because that is exactly what they are. All of the Covid vaccines are still in phase three clinical trials, with the Pfizer trial not set to finish until 2023. It is for this reason that all of the Covid vaccines are not licensed, but instead have been granted emergency use authorisation.

But perhaps more importantly, why on earth would a government, there to serve the people who elect it, want to make unlicensed, experimental treatments mandatory that have so far caused 949,287 adverse reactions and 1,332 deaths according to the 20th update on adverse reactions to the Covid vaccines reported to the MHRA Yellow Card scheme?

A Yellow Card scheme in which the MHRA state only 1% – 10% of adverse reactions are actually reported, suggesting the actual number of adverse reactions and deaths is disastrously higher.

The adverse reactions do not just include things like fever, a sore arm, or a headache like you are being advised may occur prior to receiving one of the Covid vaccines either. You are being misled, because according to the 20th update which includes data submitted to the MHRA from the 9th December 2020 through to the 9th June 2021 people are suffering extremely serious adverse reactions such as the following...

(We used the data shown in the UK Governments Analysis Print of the Pfizer vaccine {which you can find here} + Analysis Print of the AstraZeneca Vaccine {which you can find here}.)

Cardiac arrest has been reported as an adverse reaction to the Pfizer vaccine 68 times resulting in 26 deaths. In total there have been 2,615 cardiac disorders resulting in 69 deaths as a result of the Pfizer jab.

Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	68	26
Cardio-respiratory arrest	1	1
Pulseless electrical activity	3	0
Ventricular arrhythmia	4	0
Ventricular extrasystoles	11	0
Ventricular fibrillation	5	1
Ventricular tachycardia	6	0
Cardiac disorders SOC TOTAL	2615	69

Cardiac has been reported as an adverse reaction to the AstraZeneca vaccine 139 times resulting in 31 deaths. In total there have been 7,658 cardiac disorders resulting in 118 deaths as a result of the AstraZeneca jab.

Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	139	31
Cardio-respiratory arrest	2	1
Pulseless electrical activity	5	0
Ventricular arrhythmia	1	0
Ventricular extrasystoles	8	0
Ventricular fibrillation	6	0
Ventricular tachycardia	13	0
Cardiac disorders SOC TOTAL	7658	118

Deafness has been reported as an adverse reaction to the Pfizer vaccine 115 times. There have been 2,745 ear disorders as a result of the Pfizer jab.

Hearing losses		
Conductive deafness	1	0
Deafness	115	0
Deafness bilateral	5	0
Deafness neurosensory	11	0
Deafness transitory	3	0
Deafness unilateral	22	0
Hypoacusis	88	0
Sudden hearing loss	21	0

Deafness has been reported as an adverse reaction to the AstraZeneca vaccine 274 times. There have been 7,953 ear disorders reported as a result of the AstraZeneca jab.

Hearing losses		
Deafness	274	0
Deafness bilateral	13	0
Deafness neurosensory	19	0
Deafness transitory	3	0
Deafness unilateral	42	0
Hypoacusis	170	0
Neurosensory hypoacusis	1	0
Sudden hearing loss	50	0

Blindness has been reported as an adverse reaction to the Pfizer vaccine 46 times, and there have been 3,398 eye disorders reported as a result of the Pfizer jab.

Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	1	0
Blindness	46	0
Blindness transient	6	0
Blindness unilateral	8	0
Central vision loss	2	0
Sudden visual loss	2	0
Visual acuity reduced	12	0
Visual impairment	170	0
Visual pathway disorders		
Optic nerve disorder	1	0
Eye disorders SOC TOTAL	3398	0

Blindness has been reported as an adverse reaction to the AstraZeneca vaccine 229 times, and there have been 11,857 eye disorders reported as a result of the AstraZeneca jab.

Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	8	0
Blindness	229	0
Blindness day	1	0
Blindness transient	20	0
Blindness unilateral	24	0
Central vision loss	2	0
Night blindness	4	0
Sudden visual loss	5	0
Visual acuity reduced	28	0
Visual acuity reduced transiently	1	0
Visual impairment	584	0
Visual pathway disorders		
Optic nerve disorder	2	0
Optic neuropathy	7	0
Eye disorders SOC TOTAL	11857	0

Anaphylactic reactions have been reported as an adverse reaction to the Pfizer jab 328 times. During an anaphylactic reaction your immune system

releases a flood of chemicals that cause you to go into shock. Your blood pressure suddenly drops and your airways narrow, blocking breathing. Sadly 2 people have died as a result of suffering this reaction.

Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	328	2
Anaphylactic shock	26	0
Anaphylactoid reaction	18	0
Anaphylactoid shock	4	0

Anaphylactic reactions have been reported as an adverse reaction to the AstraZeneca jab 611 times. Sadly this has also resulted in 2 deaths.

Anaphylactic and anaphylactoid responses		
Anaphylactic reaction	611	2
Anaphylactic shock	105	0
Anaphylactoid reaction	21	0
Anaphylactoid shock	3	0

Strokes due to blood clots and haemorrhages have been reported as an adverse reaction to the Pfizer vaccine 387 times, sadly resulting in 29 deaths. These have included 28 cerebral haemorrhages, 30 ischaemic strokes, and 245 cerebrovascular accidents.

Central nervous system haemorrhages and cerebrovascular accidents		
Brain stem infarction	1	1
Brain stem stroke	1	0
Carotid artery thrombosis	2	0
Cerebellar haemorrhage	1	0
Cerebellar infarction	2	0
Cerebellar ischaemia	1	0
Cerebellar stroke	3	0
Cerebral artery embolism	3	1
Cerebral artery occlusion	1	0
Cerebral artery thrombosis	3	0
Cerebral haemorrhage	28	6
Cerebral infarction	22	1
Cerebral thrombosis	5	0
Cerebrovascular accident	245	12
Embolic stroke	5	0
Haemorrhage intracranial	6	1
Haemorrhagic cerebral infarction	1	0
Haemorrhagic stroke	8	3
Internal capsule infarction	1	0
Intracranial haematoma	1	0
Ischaemic cerebral infarction	1	0
Ischaemic stroke	30	1
Lacunar infarction	2	0
Lacunar stroke	2	0
Lateral medullary syndrome	1	0
Subarachnoid haemorrhage	8	3
Thalamic infarction	1	0
Thrombotic stroke	2	0

Strokes due to blood clots and haemorrhages have been reported as adverse reactions to the AstraZeneca vaccine 1,605 times, sadly resulting in 109

deaths. These have included 141 cerebral haemorrhages, 73 cerebral infarctions, and a shocking 912 cerebrovascular accidents.

Central nervous system haemorrhages and cerebrovascular accidents		
Basal ganglia haemorrhage	3	0
Basal ganglia stroke	1	0
Basilar artery occlusion	1	0
Basilar artery thrombosis	2	0
Brain stem haemorrhage	2	0
Brain stem infarction	2	2
Brain stem stroke	3	2
Carotid artery occlusion	3	0
Carotid artery thrombosis	9	1
Cerebellar haemorrhage	4	0
Cerebellar infarction	4	0
Cerebellar stroke	9	0
Cerebral artery embolism	8	0
Cerebral artery occlusion	3	0
Cerebral artery thrombosis	8	0
Cerebral haematoma	12	1
Cerebral haemorrhage	141	37
Cerebral infarction	73	3
Cerebral ischaemia	3	0
Cerebral thrombosis	33	2
Cerebral vascular occlusion	2	0
Cerebrovascular accident	912	36
Embolic stroke	19	0
Haemorrhage intracranial	46	8

As well as 31 haemorrhagic strokes, 96 subarachnoid haemorrhages, and 108 ischaemic strokes.

Reaction Name	Total	Fatal
Nervous system disorders		
Haemorrhagic cerebral infarction	2	1
Haemorrhagic stroke	31	4
Haemorrhagic transformation stroke	7	3
Internal capsule infarction	1	0
Intracranial haematoma	7	1
Intraventricular haemorrhage	6	0
Ischaemic cerebral infarction	2	0
Ischaemic stroke	108	3
Lacunar infarction	4	0
Lacunar stroke	19	0
Spinal cord haematoma	1	0
Spinal stroke	1	0
Subarachnoid haemorrhage	96	5
Thalamus haemorrhage	6	0
Thrombotic stroke	10	0
Vertebral artery occlusion	1	0

Facial paralysis has been reported as an adverse reaction to the Pfizer vaccine 216 times, whilst Bell's palsy has been reported 269 times.

Facial cranial nerve disorders		
Bell's palsy	269	0
Facial nerve disorder	3	0
Facial paralysis	216	0
Facial paresis	57	0
Facial spasm	25	0

Facial paralysis has been reported as an adverse reaction to the AstraZeneca vaccine 239 times, whilst Bell's palsy has been reported 414 times. Facial paralysis is a loss of facial movement due to nerve damage. Bell's palsy is a condition which caused weakness or paralysis of the muscles in the face.

Facial cranial nerve disorders		
Bell's palsy	414	0
Facial nerve disorder	5	0
Facial paralysis	239	0
Facial paresis	123	0
Facial spasm	28	0
Oculofacial paralysis	1	0

Paralysis has been reported as an adverse reaction to the Pfizer vaccine 68 times. There has also been 1 report of locked-in syndrome. This is a rare neurological disorder characterized by complete paralysis of voluntary muscles, except for those that control the eyes. People with locked-in syndrome are conscious and can think and reason, but are unable to speak or move.

Paralysis and paresis (excl cranial nerve)		
Diplegia	6	1
Hemiparesis	23	0
Hemiplegia	19	0
Locked-in syndrome	1	0
Monoparesis	36	0
Monoplegia	31	0
Paralysis	68	0
Paraparesis	3	0
Paresis	4	0

Paralysis has been reported as an adverse reaction to the AstraZeneca vaccine 256 times, as well as 108 reports of monoplegia. Monoplegia is paralysis that impacts one limb.

Paralysis and paresis (excl cranial nerve)		
Diplegia	24	0
Hemiparesis	84	0
Hemiplegia	29	0
Monoparesis	80	0
Monoplegia	108	0
Paralysis	256	0
Paraparesis	6	0

Spontaneous abortions a.k.a miscarriage has been reported as an adverse reaction to the Pfizer vaccine 112 times. This is despite the fact it was only

recently given approval by the JCVI to be used during pregnancy, even though there is no clinical data to support its use.

Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions not specified as induced or spontaneous</i>		
Abortion missed	2	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	110	2

Miscarriage has been reported as an adverse reaction to the AstraZeneca vaccine 86 times, this is despite the fact the JCVI **have not recommended** it be offered to pregnant women.

Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	86	1

There have been 202,036 adverse reactions reported to the MHRA Yellow Card scheme as a result of the Pfizer jab as of the 9th June 2021, these include 421 deaths.

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

Report Run Date: 14-Jun-2021

Data Lock Date: 09-Jun-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Orthostatic hypotension	16	0
<i>Vasculitides NEC</i>		
Behcet's syndrome	4	0
Granulomatosis with polyangiitis	1	0
MAGIC syndrome	1	0
Vasculitis	32	0
<i>Vena caval embolism and thrombosis</i>		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	3038	10
TOTAL REACTIONS FOR DRUG	202036	421
TOTAL REPORTS	70950	
TOTAL FATAL OUTCOME REPORTS		421

There have been 732,790 adverse reactions reported to the MHRA Yellow Card scheme as a result of the AstraZeneca jab as of the 9th June 2021, these include 885 deaths.

Case Series Drug Analysis Print

Name: COVID-19 AstraZeneca Vaccine Analysis Print

Report Run Date: 14-Jun-2021

Data Lock Date: 09-Jun-2021 19:00:03

Earliest Reaction Date: 03-Feb-1921

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Diffuse vasculitis	1	1
MAGIC syndrome	3	1
Vasculitis	113	4
Vena caval embolism and thrombosis		
Vena cava thrombosis	3	1
Vascular disorders SOC TOTAL	10392	55
TOTAL REACTIONS FOR DRUG	732790	885
TOTAL REPORTS	200860	
TOTAL FATAL OUTCOME REPORTS		885

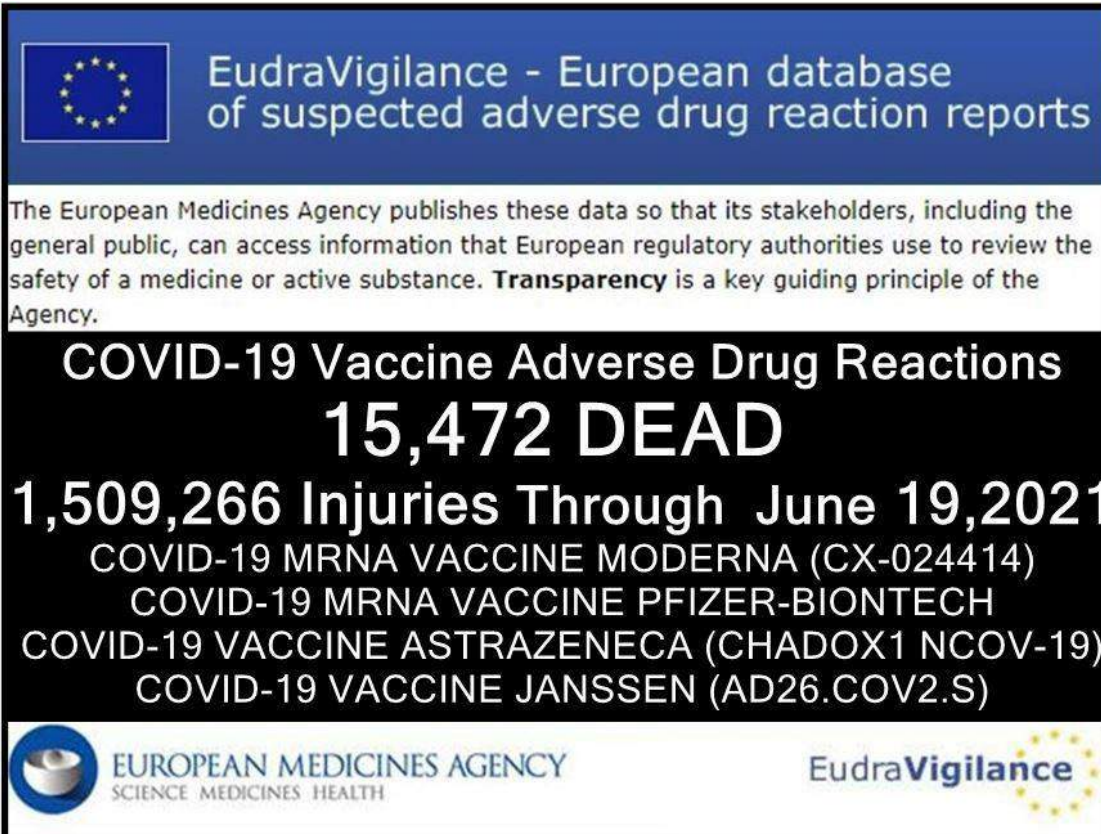
There have also been 12,042 adverse reactions reported as a result of the Moderna jab resulting in 4 deaths, and 2,419 adverse reactions where the brand of vaccine was not specified resulting in 22 deaths.

Preshant Kushan
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ANNEXURE: A36**VACCINE IMPACT**

15,472 DEAD 1.5 Million Injured (50% SERIOUS) Reported in European Union's Database of Adverse Drug Reactions for COVID-19 Shots

Posted By *susan* On June 21, 2021 @ 2:00 pm In *Headline,News* |



COVID-19 Vaccine Adverse Drug Reactions
15,472 DEAD
1,509,266 Injuries Through June 19,2021
 COVID-19 MRNA VACCINE MODERNA (CX-024414)
 COVID-19 MRNA VACCINE PFIZER-BIONTECH
 COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)
 COVID-19 VACCINE JANSSEN (AD26.COVS)

EUROPEAN MEDICINES AGENCY
 SCIENCE MEDICINES HEALTH

EudraVigilance

by **Brian Shilhavy**

Editor, Health Impact News

The European database of suspected drug reaction reports is [EudraVigilance](#),^[1] which also tracks reports of injuries and deaths following the experimental COVID-19 “vaccines.”

A subscriber from Europe recently emailed us and reminded us that this database maintained at EudraVigilance is only for countries in Europe who are part of the European Union (EU), which comprises 27 countries.

The total number of countries in Europe is much higher, almost twice as many, numbering around 50, although there are some differences of opinion as to which countries are technically part of Europe.

So as high as these numbers are, they do NOT reflect all of Europe. The actual number in Europe who are reported dead or injured due to COVID-19 shots would be much higher than what we are reporting here.

The EudraVigilance database reports that through June 19, 2021 there are **15,472 deaths and 1,509,266 injuries** reported following injections of four experimental COVID-19 shots:

- [COVID-19 MRNA VACCINE MODERNA \(CX-024414\)](#) ^[2]
- [COVID-19 MRNA VACCINE PFIZER-BIONTECH](#) ^[3]
- [COVID-19 VACCINE ASTRAZENECA \(CHADOX1 NCOV-19\)](#) ^[4]
- [COVID-19 VACCINE JANSSEN \(AD26.COV2.S\)](#) ^[5]

From the total of injuries recorded, half of them (753,657) are **serious** injuries.

*“Seriousness provides information on the suspected undesirable effect; it can be classified as ‘serious’ if it corresponds to a medical occurrence that results in **death**, is life-threatening, requires inpatient hospitalisation, results in another medically important condition, or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect.”*

A *Health Impact News* subscriber in Europe ran the reports for each of the four COVID-19 shots we are including here. This subscriber has volunteered to do this, and it is a lot of work to tabulate each reaction with injuries and fatalities, since there is no place on the [EudraVigilance](#) ^[6] system we have found that tabulates all the results.

Since we have started publishing this, others from Europe have also calculated the numbers and confirmed the totals.*

Here is the summary data through June 19, 2021.

Total reactions for the experimental mRNA vaccine **Tozinameran** (code **BNT162b2, Comirnaty**) from **BioNTech/ Pfizer: 7,420 deaths** and **560,256 injuries** to 19/06/2021

- 16,133 Blood and lymphatic system disorders **incl. 81 deaths**
- 12,637 Cardiac disorders **incl. 964 deaths**
- 101 Congenital, familial and genetic disorders **incl. 6 deaths**
- 7000 Ear and labyrinth disorders **incl. 4 deaths**
- 265 Endocrine disorders **incl. 1 death**
- 8,122 Eye disorders **incl. 17 deaths**
- 51,030 Gastrointestinal disorders **incl. 348 deaths**
- 155,486 General disorders and administration site conditions **incl. 2,290 deaths**
- 468 Hepatobiliary disorders **incl. 31 deaths**
- 6,110 Immune system disorders **incl. 32 deaths**
- 17,549 Infections and infestations **incl. 762 deaths**
- 6,275 Injury, poisoning and procedural complications **incl. 104 deaths**
- 13,249 Investigations **incl. 285 deaths**
- 4,162 Metabolism and nutrition disorders **incl. 139 deaths**
- 79,125 Musculoskeletal and connective tissue disorders **incl. 88 deaths**
- 325 Neoplasms benign, malignant and unspecified (incl. cysts and polyps) **incl. 23 deaths**
- 100,895 Nervous system disorders **incl. 780 deaths**
- 384 Pregnancy, puerperium and perinatal conditions **incl. 10 deaths**
- 107 Product issues
- 9,928 Psychiatric disorders **incl. 105 deaths**
- 1,765 Renal and urinary disorders **incl. 115 deaths**
- 2,696 Reproductive system and breast disorders **incl. 3 deaths**
- 23,689 Respiratory, thoracic and mediastinal disorders **incl. 848 deaths**
- 26,641 Skin and subcutaneous tissue disorders **incl. 66 deaths**
- 846 Social circumstances **incl. 10 deaths**

- 281 Surgical and medical procedures **incl. 19 deaths**
- 14,987 Vascular disorders **incl. 289 deaths**
- **Total reactions for the experimental mRNA vaccine mRNA-1273(CX-024414) from Moderna: 4,147 deaths and 122,643 injuries to 19/06/2021**
- 2,239 Blood and lymphatic system disorders **incl. 29 deaths**
- 3,315 Cardiac disorders **incl. 446 deaths**
- 39 Congenital, familial and genetic disorders **incl. 3 deaths**
- 1,454 Ear and labyrinth disorders
- 82 Endocrine disorders **incl. 1 death**
- 1,883 Eye disorders **incl. 7 deaths**
- 10,655 Gastrointestinal disorders **incl. 142 deaths**
- 33,936 General disorders and administration site conditions **incl. 1,759 deaths**
- 209 Hepatobiliary disorders **incl. 11 deaths**
- 1,117 Immune system disorders **incl. 5 deaths**
- 3,835 Infections and infestations **incl. 234 deaths**
- 2,480 Injury, poisoning and procedural complications **incl. 77 deaths**
- 2,670 Investigations **incl. 89 deaths**
- 1,297 Metabolism and nutrition disorders **incl. 85 deaths**
- 15,131 Musculoskeletal and connective tissue disorders **incl. 77 deaths**
- 128 Neoplasms benign, malignant and unspecified (incl. cysts and polyps) **incl. 15 deaths**
- 21,684 Nervous system disorders **incl. 424 deaths**
- 255 Pregnancy, puerperium and perinatal conditions **incl. 2 death**
- 20 Product issues
- 2,437 Psychiatric disorders **incl. 69 deaths**
- 807 Renal and urinary disorders **incl. 52 deaths**
- 459 Reproductive system and breast disorders **incl. 1 death**
- 5,640 Respiratory, thoracic and mediastinal disorders **incl. 399 deaths**
- 6,538 Skin and subcutaneous tissue disorders **incl. 28 deaths**
- 504 Social circumstances **incl. 13 deaths**
- 397 Surgical and medical procedures **incl. 38 deaths**
- 3,432 Vascular disorders **incl. 141 deaths**
- **Total reactions for the experimental vaccine AZD1222/VAXZEVRIA (CHADOX1 NCOV-19) from Oxford/ AstraZeneca: 3,364 deaths and 793,036 injuries to 19/06/2021**
- 9,136 Blood and lymphatic system disorders **incl. 132 deaths**
- 12,135 Cardiac disorders **incl. 396 deaths**
- 95 Congenital, familial and genetic disorders **incl. 2 deaths**
- 8,797 Ear and labyrinth disorders
- 309 Endocrine disorders **incl. 2 deaths**
- 13,459 Eye disorders **incl. 12 deaths**
- 81,806 Gastrointestinal disorders **incl. 161 deaths**
- 212,663 General disorders and administration site conditions **incl. 891 deaths**
- 525 Hepatobiliary disorders **incl. 25 deaths**
- 3,085 Immune system disorders **incl. 11 deaths**
- 17,791 Infections and infestations **incl. 217 deaths**
- 7,854 Injury, poisoning and procedural complications **incl. 77 deaths**
- 16,731 Investigations **incl. 79 deaths**
- 9,765 Metabolism and nutrition disorders **incl. 50 deaths**
- 123,637 Musculoskeletal and connective tissue disorders **incl. 45 deaths**

- 332 Neoplasms benign, malignant and unspecified (incl. cysts and polyps) **incl. 8 deaths**
 - 169,286 Nervous system disorders **incl. 532 deaths**
 - 223 Pregnancy, puerperium and perinatal conditions **incl. 4 deaths**
 - 103 Product issues
 - 14,931 Psychiatric disorders **incl. 27 deaths**
 - 2,809 Renal and urinary disorders **incl. 29 deaths**
 - 5,967 Reproductive system and breast disorders
 - 26,631 Respiratory, thoracic and mediastinal disorders **incl. 387 deaths**
 - 36,457 Skin and subcutaneous tissue disorders **incl. 22 deaths**
 - 772 Social circumstances **incl. 4 deaths**
 - 671 Surgical and medical procedures **incl. 16 deaths**
 - 17,066 Vascular disorders **incl. 235 deaths**
- Total reactions for the experimental COVID-19 vaccine JANSSEN (AD26.COV2.S) from Johnson & Johnson: 541 deaths and 33, 331 injuries to 19/06/2021**
- 306 Blood and lymphatic system disorders **incl. 16 deaths**
 - 496 Cardiac disorders **incl. 56 deaths**
 - 14 Congenital, familial and genetic disorders
 - 177 Ear and labyrinth disorders
 - 8 Endocrine disorders **incl. 1 death**
 - 383 Eye disorders **incl. 3 deaths**
 - 3,086 Gastrointestinal disorders **incl. 23 deaths**
 - 8,761 General disorders and administration site conditions **incl. 137 deaths**
 - 52 Hepatobiliary disorders **incl. 4 deaths**
 - 85 Immune system disorders
 - 392 Infections and infestations **incl. 13 deaths**
 - 320 Injury, poisoning and procedural complications **incl. 8 deaths**
 - 2,003 Investigations **incl. 37 deaths**
 - 184 Metabolism and nutrition disorders **incl. 10 deaths**
 - 5,718 Musculoskeletal and connective tissue disorders **incl. 17 deaths**
 - 16 Neoplasms benign, malignant and unspecified (incl. cysts and polyps)
 - 7,093 Nervous system disorders **incl. 68 deaths**
 - 9 Pregnancy, puerperium and perinatal conditions **incl. 1 death**
 - 9 Product issues
 - 355 Psychiatric disorders **incl. 5 deaths**
 - 119 Renal and urinary disorders **incl. 8 deaths**
 - 114 Reproductive system and breast disorders
 - 1,130 Respiratory, thoracic and mediastinal disorders **incl. 43 deaths**
 - 804 Skin and subcutaneous tissue disorders **incl. 2 deaths**
 - 72 Social circumstances **incl. 3 deaths**
 - 336 Surgical and medical procedures **incl. 26 deaths**
 - 1,289 Vascular disorders **incl. 60 deaths**

Last Update: Jun 19 2021	Reported Cases	Fatalities	% fatalities to cases	All Multiple Symptoms	Serious injuries	% serious to ALL
Astrazeneca	292 283	3 364	1,15%	793 036	438 722	55,32%
Pfizer-BioNTech	238 435	7 420	3,11%	560 256	235 109	41,96%
Moderna	49 323	4 147	8,41%	122 643	68 569	55,91%
Janssen	11 276	541	4,80%	33 331	11 257	33,77%
Total:	591 317	15 472	2,62%	1 509 266	753 657	49,94%

*These totals are estimates based on reports submitted to [EudraVigilance](#) ^[6]. Totals may be much higher based on percentage of adverse reactions that are reported. Some of these reports may also be reported to the individual country's adverse reaction databases, such as the U.S. VAERS database and the UK Yellow Card system. The fatalities are grouped by symptoms, and some fatalities may have resulted from multiple symptoms.

Preshant Bhusan

(TRUE COPY)

IN THE HIGH COURT OF GUJARAT AT AHMEDABAD**R/SPECIAL CIVIL APPLICATION NO. 8309 of 2021**

=====

YOGENDRA KUMAR

Versus

INDIAN AIR FORCE & 1 other(s)

=====

Appearance:

MR GUNJAN SINGH for MR AUM M KOTWAL(7320) for the Petitioner

MS SHREE KOTWAL(11177) for the Petitioner(s) No. 1

for the Respondent(s) No. 1,2

=====

CORAM: **HONOURABLE MR. JUSTICE A.J.DESAI**

and

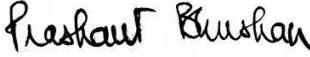
HONOURABLE DR. JUSTICE A. P. THAKER**Date : 22/06/2021****ORAL ORDER****(PER : HONOURABLE MR. JUSTICE A.J.DESAI)**

NOTICE returnable on 01.07.2021.

Till then, no coercive action shall be taken against the petitioner, who is at present not willing to take vaccine.

(A.J. DESAI, J.)**(DR. A. P. THAKER, J.)**

Ajay



(TRUE COPY)

ANNEXURE: A38

Serial No.01 Regular List
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HIGH COURT OF MEGHALAYA
AT SHILLONG

PIL No.6/2021

Date of Order: 23.06.2021

Registrar General, High Court of Meghalaya	Vs.	State of Meghalaya
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Coram:

Hon'ble Mr. Justice Biswanath Somadder, Chief Justice
Hon'ble Mr. Justice H.S. Thangkhiew, Judge

Appearance:

For the Petitioner/Appellant(s)	: –
For the Respondent(s)	: Mr. A Kumar, Advocate General with Mr. S Sen Gupta, Addl.Sr.GA, Mr. AH Kharwanlang, GA, Mr. Chetan Joshi, Adv Mr. Shaurya Sahay, Adv Mr. Aditya Shankar Pandey, Adv

i)	Whether approved for reporting in Law journals etc.:	Yes/No
ii)	Whether approved for publication in press:	Yes/No

ORDER: (per Biswanath Somadder, the Hon'ble, the Chief Justice)

It has been brought to the notice of this High Court that the State of Meghalaya, through various orders of the Deputy Commissioners, has made it mandatory for shopkeepers, vendors, local taxi drivers and others to get themselves vaccinated before they can resume their businesses. Whether vaccination can at all be made mandatory and whether such mandatory action can adversely affect the right of a citizen to earn his/her livelihood, is an issue which requires consideration.

At the outset, it must be stated clearly and unequivocally that vaccination is need of the hour – nay, an absolute necessity – in order to overcome this global pandemic which is engulfing our world. However, the issue, as stated in the earlier paragraph, requires to be clearly answered.

In order to answer the issue, at first, we need to look at certain fundamental principles which govern the field.

Article 21 encompasses within its fold, right to health, as a fundamental right. By that same analogy, right to health care, which includes vaccination, is a fundamental right. However, vaccination by force or being made mandatory by adopting coercive methods, vitiates the very fundamental purpose of the welfare attached to it. It impinges on the fundamental right(s) as such, especially when it affects the right to means of livelihood which makes it possible for a person to live. As held in *Olga Tellis & Ors vs. Bombay Municipal Corporation & Ors* reported at AIR 1986 SC 180 = (1985) 3 SCC 545, right to life includes right to the means of livelihood. Any action of the State which is in absolute derogation of this basic principle is squarely affected by Article 19(1)(g). Although, Article 19(6) prescribes “reasonable restrictions” in the “interest of general public”, the present instance is exemplary and clearly distinguishable. It affects an individual’s right, choice and liberty significantly more than affecting the general public as such or for that matter, the latter’s interests being at stake because of the autonomous decision of an individual *human being* of choosing not to be vaccinated. It is more about striking the right balance between an individual’s right vis-à-vis the right of the public at large. However, in substantiation of Mill’s theory of the liberty to exercise one’s right until it impinges on the right of another; here too, the “welfare State” is attempting to secure the rights of others, which – though legitimate – is palpably excessive owing to the procedure adopted by it. Another pivotal question emerges as to whether any notification/order published by the State Government and/or its authority can be understood as a prescription by “law” for the purposes of prohibiting a greater degree of rights; i.e., fundamental rights. In other words, can a State Government and/or its authority issue any notification/order which is likely to have a direct effect on the fundamental rights of its citizens especially on a subject matter that concerns both public health and the fundamental rights of the individual person.

The issue here essentially centres around a question on the lawmaking power of the State Government, which, even though permitted by Entry 6, List II of the Seventh Schedule, has to be in consonance with the

fundamental right to life and livelihood of an individual. In this case, there is a clear lack of legitimacy in prohibiting freedom of carrying on any occupation, trade or business amongst a certain category or class of citizens who are otherwise entitled to do so, making the notification/order ill-conceived, arbitrary and/or a colourable exercise of power. A notification/order of the State certainly cannot put an embargo and/or fetter on the *fundamental* right to life of an individual by stripping off his/her right to livelihood, except according to the procedure established by law. Even that procedure is required to be reasonable, just and fair (see *Olga Tellis*, supra). Till now, there has been no legal mandate whatsoever with regard to coercive or mandatory vaccination in general and the Covid19 vaccination drive in particular that can prohibit or take away the livelihood of a citizen on that ground.

In the “frequently asked questions” (FAQs) on COVID-19 vaccine prepared and uploaded by the Ministry of Health and Family Welfare, Government of India, in its official website, the question which appears under serial number 3 reads, “Is it mandatory to take the vaccine?” The “potential response”, which is provided in the official website reads, “Vaccination for COVID-19 is voluntary. However, it is advisable to receive the complete schedule of COVID-19 vaccine for protecting oneself against this disease and also to limit the spread of this disease to the close contacts including family members, friends, relatives and co-workers.”

In this context, around one hundred and seven (107) years ago, in *Schloendorff v Society of New York Hospitals* reported at (1914) 211 NY 125 = 105 NE 92; 1914 NY Justice Cardozo ruled that ‘every human being of adult years and sound mind has a right to determine what shall be done with their body’. Thus, by use of force or through deception if an unwilling capable adult is made to have the ‘flu vaccine would be considered both a crime and tort or civil’ wrong, as was ruled in *Airedale NHS Trust v Bland* reported at 1993 AC 789 = (1993) 2 WLR 316 = (1993) 1 All ER 821, around thirty years (30) ago. Thus, coercive element of vaccination has, since the early phases of the initiation of vaccination as a preventive measure against several diseases, have been time and again not only

discouraged but also consistently ruled against by the Courts for over more than a century.

There are several ambiguities on the procedural and substantive aspects of the concerned notification/order. Doubts are cast on whether *coercive* assertion of one's fundamental right can tend to abrogate another's equally placed fundamental right. Question also arises whether fundamental right can be forcefully imposed even if the beneficiary is not inclined to its exercise, because, if the latter is undertaken, then there is a risk of running into infringing on the fundamental right to privacy and exercise of personal liberty. Furthermore, whether to subject oneself to an intrusion of his/her body, even if of minor intensity, e.g., through a needle, concerns issues of personal and bodily autonomy and bodily integrity, similar to abortion rights or non-sterilization rights or even sex reassignment surgeries, irrespective of what consequences the individual might be inviting. This finds mention in decisions of the European Commission and Court of Human Rights [X vs. Netherlands of 1978 (decision rendered on 4th December, 1978); X vs. Austria of 1979 (decision rendered on 13th December, 1979)] which has become truer in the present times across the world than ever before. Compulsory administration of a vaccine without hampering one's right to life and liberty based on informed choice and informed consent is one thing. However, if any compulsory vaccination drive is coercive by its very nature and spirit, it assumes a different proportion and character.

In our view, the burden lies on the State to disseminate and sensitize the citizens of the entire exercise of vaccination with its pros and cons and facilitate informed decision making particularly in a situation where the beneficiaries are skeptical, susceptible and belonging to vulnerable/marginalised section of the society, some of whom are also gullible members of the indigenous communities who are constantly being fed with deliberate misinformation regarding the efficacy of vaccination by some persons/organisations with oblique motives. The welfare nature of the State isn't for coercive negative reinforcement by seizing their right to livelihood, proscribing them to earn from their occupation and/or profession without any justification in the garb of public interest, but lies in walking

together with concerted efforts attempting to effectuate a social order as mandated under Article 38 by approaching the people directly by engaging them in one-to-one dialogues and dwelling on the efficiency and the positive aspects of administering of the vaccine without compromising its duty under Article 47 nor abrogating its duty to secure adequate means of livelihood under Article 39(a). Therefore, right to and the welfare policy for vaccination can never affect a major fundamental right; i.e., right to life, personal liberty and livelihood, especially when there exists no reasonable nexus between vaccination and prohibition of continuance of occupation and/or profession. A harmonious and purposive construction of the provisions of law and principles of equity, good conscience and justice reveals that mandatory or forceful vaccination does not find any force in law leading to such acts being liable to be declared *ultra vires ab initio*.

At this stage, learned Advocate General draws our attention to certain guidelines issued by the Principal Secretary to the Government of Meghalaya, Health and Family Welfare Department, yesterday, i.e., 22nd June, 2021, to all the Deputy Commissioners of the districts of Meghalaya on the measures required to be taken by the districts for addressing the issue of vaccine hesitancy. Perusing the same, it appears that the Principal Secretary to the Government of Meghalaya, Health and Family Welfare Department, has observed inter alia that for public health administration, indigenous States like Meghalaya poses distinct challenges while mobilising people and introducing any new interventions. In such situations, the approach towards effecting any kind of behavioural change needs to be ‘*adaptive*’ in nature, meaning thereby that the people need to be mobilised and convinced to see the impact of the new intervention for greater acceptance among the communities. It has also been advised by the Principal Secretary to the Government of Meghalaya, Health and Family Welfare Department, in the said guidelines that the orders in the districts have to be seen as a “**persuasive advisory**” and *not as a coercion* with regards to the issue of vaccination.

The Principal Secretary to the Government of Meghalaya, Health and Family Welfare Department, while issuing the guidelines dated 22nd June,

2021, has also laid down 7(seven) points that are required to be considered for effecting change in the COVID vaccine compliance in the respective districts of Meghalaya. The Principal Secretary has clearly stated that the existing orders on vaccine compliance may be modified in the light of the new policy directions as spelt out in the guidelines dated 22nd June, 2021 and requirement of vaccination should be directory and not mandatory.

This, in our view is a step in the right direction.

The learned Advocate General has further placed an order issued by the Deputy Commissioner, East Khasi Hills District, Shillong, yesterday, i.e., 22nd June, 2021, following the new guidelines issued by the Principal Secretary to the Government of Meghalaya, Health and Family Welfare Department, yesterday. A plain reading of this order reveals the same to be quite in sync with the observations made hereinbefore by this Court read with new guidelines issued yesterday by the Principal Secretary, Government of Meghalaya, Health and Family Welfare Department. We are of the view that this order is required to be complied with by all shops/establishments/local taxis/auto-rickshaws/maxi cabs and buses, forthwith.

In addition thereto, we issue the following directions so that the public at large are provided with an option of making an informed choice:-

- (i) All shops/establishments/local taxis/auto-rickshaws/maxi cabs and buses should display prominently at a conspicuous place, a sign, "VACCINATED", in the event all employees and staff of the concerned shop/establishment are vaccinated. Similarly, in the case of local taxis/auto-rickshaws/maxi cabs and buses where the concerned driver or conductor or helper(s) are vaccinated.
- (ii) All shops/establishments/local taxis/auto-rickshaws/maxi cabs and buses should display prominently at a conspicuous place, a sign, "NOT VACCINATED", in the event all the employees and staff of the concerned shop/establishment are not vaccinated. Similarly, in the case of local taxis/auto-rickshaws/maxi cabs and buses where the concerned driver or conductor or helper(s) are not vaccinated.

The actual dimension of the signs, “VACCINATED” or “NOT VACCINATED” and the conspicuous place where such sign is required to be affixed/displayed shall be decided by the concerned authority of the State. In the event, any shops/establishments/local taxis/auto-rickshaws/maxi cabs and buses flouts the above directions, the concerned authority of the State shall immediately direct its closure/stoppage of plying.

So far as vaccine hesitation issue is concerned, the same is required to be dealt with by the State Government in the manner specified in its new guidelines issued yesterday by the Principal Secretary, Health and Family Welfare Department, Government of Meghalaya, read with the observations made by us hereinbefore. This Court shall monitor this issue closely so that the State Government is able to overcome the vaccine hesitation problem at the earliest and all eligible persons in the State of Meghalaya are vaccinated well within the timeframe as may be specified by the State.

In the event, there is any attempt made by any person/organisation to spread misinformation regarding the efficacy of vaccination amongst the people of this State, the concerned authority of the State shall immediately step in and proceed against such person/organisation in accordance with law. The concerned authority of the State shall also bring such instances to the notice of this Court.

So far as the other issue with regard to the method of implementation of the Government Welfare Schemes meant for the marginalised section of the society is concerned, the learned Advocate General has placed an order dated 22nd June, 2021, issued by the Chief Secretary to the Government of Meghalaya. We request the learned Registrar General to intimate the Member Secretary of the Meghalaya State Legal Services Authority, Shillong, with regard to the said order dated 22nd June, 2021. The Member Secretary of the Meghalaya State Legal Services Authority, Shillong, shall bring the said order to the notice of all the Secretaries of the District State Legal Services Authorities in the State of Meghalaya who shall enquire and find out as to whether the concerned departments are actually taking steps to ensure that the Government Welfare Schemes for the marginalised section of the society are being properly and effectively implemented in a time

bound manner in accordance with the guidelines of the respective schemes. The Secretaries of all the District State Legal Services Authorities shall submit their respective reports to the Member Secretary, Meghalaya State Legal Services Authority, Shillong, within a period of four weeks from date so that the Member Secretary can compile the same and place the compilation before this Court through the learned Registrar General.

List this matter next Wednesday, i.e., 30th June, 2021 for further consideration.

(H.S. Thangkhiew)
Judge

(Biswanath Somadder)
Chief Justice

Meghalaya
23.06.2021
"Lam AR-PS"



Preshant Bhusan
(TRUE COPY)