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### **Proforma for First Listing**

SECTION \_\_\_\_\_

The case pertains to (Please tick/check the correct box):

- Central Act: The Constitution of India
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- State Act: (Title) N.A
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- Impugned Interim Order: (Date) N.A
- Impugned Final Order: N.A
- Name of Judges: N.A
- Tribunal/Authority: N.A
- 1. Nature of matter:  $\Box$  Civil  $\Box$  Criminal
- 2. (a) Petitioner/appellant No.1: Rachana Gangu
  - (b) E-mail ID: N.A
  - (c) Mobile phone number: N.A
- 3. (a) Respondent No.1: Union of India
  - (b) e-mail ID: N.A
  - (c) Mobile phone number: N.A
- 4. (a) Main category classification: N.A(b) Sub classification: N.A
- 5. Not to be listed before: N.A

Similar disposed of matter with citation, if any, & case a. details: No similar matter disposed of Similar pending matter with case details: No similar matter b. pending 7. **Criminal Matters:** (a) Whether accused/convict has surrendered: Yes No (b) FIR No. N.A Date: N.A (c) Police Station: N.A (d) Sentence Awarded: N.A (e) Sentence Undergone: N.A 8. Land Acquisition Matters: (a) Date of section 4 notification: N.A (b) Date of section 6 notification: N.A (c) Date of section 17 notification: N.A 9. Tax Matters: State the tax effect: N.A 10. Special Category (first petitioner/appellant only):  $\Box$  Senior citizen>65 years  $\square$  SC/ST □ Woman/Child  $\square$  Disabled  $\Box$ Legal Aid case  $\Box$  In custody 11. Vehicle Number (in case of Motor Accident Claim matters): N.A

Date:

fmf.

AOR for petitioner (s)/ appellant(s) (Name): Mr. Satya Mitra Registration No. 1852 <u>satyamitra2003@gmail.com</u>

#### **IN THE MATTER OF:**

Rachana Gangu & Anr.

...Petitioners

Versus

Union of India & Ors.

...Respondents

#### PAPERBOOK

#### (FOR INDEX PLEASE SEE INSIDE)

I.A. No. \_\_\_\_\_ of 2021: Application seeking exemption from filing notarised affidavit.

ADVOCATE FOR PETITIONERS: SATYA MITRA

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#### **SYNOPSIS**

- 1. The Petitioners No. 1 & 2 are compelled to file the present Writ Petition due to the untimely, tragic and avoidable demise of their 18 year and 20 year old daughters respectively. Petitioner No. 1's daughter received the first dose of the Covishield Covid-19 vaccine on 29.5.2021 and lost her life a few weeks later on 19.6.2021. Petitioner No. 2's daughter received the first dose of the Covishield Covid-19 vaccine on 8.6.2021 and lost her life a few weeks later on 10.7.2021. The Petitioners' respective daughters were healthy and bright young women with no known illnesses or physical disorders. Yet they started experiencing severe AEFI (Adverse Effects Following Immunization) soon after they received the vaccine shot. Petitioner No. 1's daughter suffered rapid decrease in her platelet count, incessant headache, vomiting and seizures, and physical, mental and emotional trauma, before she eventually lost her life while on life support, less than three weeks after she received the vaccine shot. Petitioner No. 2's daughter suffered from heightened immunomarkers and WBC, fever, trouble in throat, arthralgia, headache and myalgia, and exertional dyspnoea before she eventually lost her life. It is pertinent to note neither Petitioners nor their daughters were informed in advance of the risk of such severe AEFI and their informed consent was not taken before administering of the vaccine.
- 2. Having suffered the loss of their young daughters, the Petitioners are filing this Writ Petition seeking a writ, order or direction for appointment of an expert medical board, independent of the Government, to forthwith

inquire into and investigate into the deaths of the daughters of Petitioners No. 1 & 2 and to share the report of the investigation with the Petitioners, as well as a writ, order or direction to the said expert medical board to prepare a protocol for early detection and timely treatment for the AEFI due to Covid-19 vaccine; and compensation to the Petitioners.

3. The sequence of events leading to the present petition are as under:

Date	Particulars
29.5.2021	Petitioner No. 1's daughter administered Covishield
	vaccination on her left arm. After the vaccination she was
	advised to take paracetamol every six hours. After 2
	hours of administering Covishield vaccination, the
	Petitioner No. 1's daughter started complaining of
	headache and body pain. Furthermore, around 4.00 pm
	she started having a fever as well. In the late evening her
	fever did not subside and went up to 102.7 and after that
	she was given Paracetamol. Even after taking the
	prescribed medicine fever didn't come down to normal.
30.5.2021	Her fever didn't come down and she started to have
	severe body ache as well as headaches. Petitioner No. 1
	tried to follow the advice given at the vaccination center
	and started giving her daughter paracetamol every six to
	eight hours. As a result in order to reduce the fever the
	Petitioner No. 1's daughter took around three to four
	paracetamol in 2 days after vaccination.

## Brief facts relating to Petitioner No.1's Daughter

30.5.2021-	Petitioner's daughter from the evening of 30.5.2021	
4.6.2021	started feeling better till the next 5 days and was able to	
	perform regular tasks and was living a normal life.	
5.6.2021	However, on 5.6.2021 the Petitioner No. 1's daughter	
	woke up around 3.30 am with a headache and started to	
	scratch her head near the hairline of the head till the back.	
	On the said night Petitioner No. 1's daughter could not	
	sleep properly due to severe headache and woke up at	
	about 12 noon. After she woke up, she also complained	
	that her left thumb, and one of the small toes on her left	
	foot were really sore and hurting. She was in extreme	
	pain.	
	Later in the day she started complaining about itching in	
	her palms, and fingertips were tingly and numb. The	
	Petitioner No. 1 booked an online doctor's appointment	
	with Apollo 24/7 with Dr. Dhanraj K. K., who prescribed	
	Avil (25mg) for allergic reaction and Calpol(650mg) for	
	pain and advised that if symptoms do not get better within	
	two days, the prescribed blood tests should be done.	
6.6.2021	The symptoms subsisted and in addition she started	
	complaining about burning pain in her hand and feet. Her	
	palms were really hot and red.	
7.6.2021	After two days of continuous suffering and no sign of	
	relief, Petitioner No. 1 decided to take the blood tests	
	advised by the Doctor during online consultation.	

Petitioner No. 1's daughter started to show even more
symptoms such as pink spots underneath her palms and
skins.
Later around 8.50 pm, Vijaya Diagnostics, where
Petitioner No. 1's daughter gave blood for testing, called
and stated that her platelets were extremely low.
It was confirmed by Vijaya Diagnostics that her platelets
were really low at 40,000 only.
Petitioner No. 1 booked another online doctor's
appointment with Apollo 24/7 with Dr. Anish Anand.
Upon learning about the new symptoms the said doctor
suggested that it might be a viral infection like a bone and
joint infection and told Petitioner not to worry and that
Petitioner's No. 1's daughter seemed to be doing fine and
advised them to go for a retest and few more tests

8.6.2021	Later at around 6 pm Petitioner No. 1's daughter started
	feeling extremely low with extreme headache, vomits,
	purple patch on her eyelid, dehydrated lips and due to no
	response from the online consultation app, Petitioner No.
	1 rushed her daughter in the night to the Emergency
	Room at Apollo Hospital, Film Nagar, Hyderabad.
	Petitioner No. 1's daughter was admitted and several tests
	were conducted on her and was referred to a neurologist
	asking for an MRI to be done.
	MRI could not be completed due to severe discomfort felt
	by Petitioner No. 1's daughter, however during the MRI

including Dengue, the following day.

8.6.2021

	process technician told Petitioner No. 1 that there must be
	a problem in the brain and her daughter needed to be
	admitted in the hospital.
9.6.2021	Around 6:30 am, a team of doctors who were looking
	after the case of Petitioner No. 1's daughter informed the
	Petitioner No. 1 that the Covid test was negative but
	platelets went down even further to 30,000 and
	incomplete MRI reports suggested that there seems to be
	problem in victim's brain hence immediate investigation
	should take place.
	After this the Petitioner No. 1's daughter was to be shifted
	into the ICU and meanwhile Petitioner No. 1's daughter
	got seizures. After a severe seizure she was put on a
	ventilator right away.
	Doctors confirmed via CT scan that she had blood clots
	in right frontal lobe of her brain which caused extensive
	hemorrhage and the pressure from the said hemorrhage is
	damaging her brain, and informed that they have to do an
	emergency surgery to release the brain pressure. As a
	result, a brain surgery called craniectomy was performed
	in order to release the brain pressure.
10.6.2021	Dr. Alok Ranjan, Neurosurgeon who performed the
	surgery on Petitioner No. 1's daughter informed
	Petitioner No. 1 that their daughter had been diagnosed
	with a condition called CVST-Cerebral Venous Sinus
	Thrombosis and also mentioned that her chances of
	survival were only 50%, and that even if she survived, her
	• • •

	quality of life will be affected as her brain had been
	extensively damaged.
10.6.2021-	After the surgery, Petitioner No. 1's daughter was shifted
14.6.2021	to Neuro ICU and was under constant observation. Over
	six days after the surgery, several tests took place in order
	to get the proper treatment of Petitioner's daughter for the
	clots. In between the ongoing tests and to identify proper
	cause of the clots, Petitioner heard from the doctors that
	their daughter's condition was "Vaccine Induced
	Thrombotic Thrombocyopenia" (VITT) as they were
	unable to find any links to the present condition of
	Petitioner' daughter.
15.6.2021	Doctors informed Petitioner No. 1 that their daughter got
	some kind of shock and as a result of this the little pupil
	movement that she had after her brain surgery was also
	gone and there were no electrical signals or active brain
	stem activity in her brain and hence she was now
	completely dependent on ventilator. Thus she was
	declared brain dead by doctors. The doctors explained
	that this meant that she was clinically dead and there was
	no possibility that she was going to come back to life.
	Thus, Petitioner No. 1 was given certain options such as
	to wait until rest of her daughter's body ceased to
	function and let her pass away, or that she could be shifted
	home, where the doctors would remove her life support
	and let her pass away as rest of her body stops to function,
	or they could donate her organs as her organs were still

	in perfect condition and could be donated to save	
	someone else's lives.	
15.6.2021-	Over the next 4 days Petitioner No. 1 researched about	
19.6.2021	various other treatments looking for a way to save her	
	daughter's life. However, nothing was in their favor as	
	there were no signs of improvement as there was no blood	
	flow from the neck onwards to the brain.	
19.6.2021	The doctors informed Petitioner No. 1 that her daughter's	
	brain was starting to degenerate and liquify and told her	
	that it was unethical to continue to keep her daughter in	
	that condition. In medical terms the doctor said that a	
	person never comes back from brain dead and that the	
	Petitioner No. 1 should decide about the next steps, as	
	there was nothing left to be medically done to bring her	
	back to life. Thus Petitioner No. 1 decided to donate the	
	organs of her daughter and allowed the doctors to remove	
	her life support and let her pass away.	
20.6.2021	Autopsy was done by a Professor from Osmania Medical	
	College on behalf of the Government. The reports have	
	still not been given to the Petitioner No. 1 even after	
	repeated requests by the Petitioner No. 1 as well as from	
	the hospital where her daughter was admitted.	

# Brief facts relating to Petitioner No. 2's Daughter

Date	Particulars	
8.6.2021	Petitioner No. 2's daughter was administered the	
	Covishield vaccine and after vaccination she was	
	experiencing tiredness, and had mild fever in the night.	
17.6.2021		
	Petitioner's daughter started sensing trouble in throat and	
	thus gargled with salt water. She went to bed with mild	
	fever.	
18.6.2021	Petitioner No. 2's daughter woke up with serious	
	symptoms. She had high fever, along with severe throat	
	pain, arthralgia, headache and myalgia	
19.6.2021	An RTPCR test with Microbiological laboratories was	
	conducted to test the for COVID-19. The test results	
	came negative.	
20.6.2021	The Petitioner No. 2's daughter was taken to Aroghya	
	Nursing Home. The Doctor checked and gave her liquid	
	medicines saying that her throat is very much inflamed	
	and advised Petitioner No. 2 not to give his daughter	
	anything solid to eat.	
21.6.2021	Since there wasn't much improvement in her condition,	
	the Petitioner No. 2's daughter was again taken to the	
	hospital where the Doctor asked to admit her.	
24.6.2021	Petitioner No. 2 via call reported the adverse effects to	
	the Serum Institute of India (SII).	
25.6.2021	As the treatment at Aroghya Nursing Home did not yield	
	much result, and the severe difficulty in walking due to	
	pain and the incessant fever continued, and the	

	inflammatory markers continued to be high in blood
	tests, Petitioner No. 2's daughter was shifted to PSG
	Hospital, a speciality hospital with an attached Medical
	college. She also had exertional dyspnea by now. There
	were a variety of investigations including CT Scans,
	Echo, PET scans, etc. conducted apart from almost daily
	blood tests. The blood tests continuously gave
	heightened immunomarkers and WBC. She was put on a
	7 day antibiotics course.
4.7.2021	She was administered anticoagulants and steroids which
	gave her some relief. However the fever didn't go away
	and it was more pronounced in the night.
6.7.2021	At night she had fever with severe chills and shaking of
	whole body.
7.7.2021	Doctors began administering IV IgG. Unfortunately
	there was a sudden drop in her health on that afternoon,
	and her BP, pulse, O2 level all started dropping
	alarmingly. She was put on O2, and was rushed to the
	ICU. From there it was downhill and she never
	recovered.
10.7.2021	Petitioner No. 2's daughter passed away.
22.7.2021	In response to a series of emails written by the Petitioner
	No. 2, Dr. Sumit Tandon, Senior Manager, Clinical
	Research and Pharmacovigilance Dept., Serum Institute
	of India Pvt. Ltd., 212/2, Hadapsar, Pune - 411 028,
	< <u>sumit.tandon@seruminstitute.com</u> >, wrote: Dear Mr
	Venugopalan, Thanks for sharing all the reports.
	Currently, Covid-19 infection is considered as the cause
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of Multisystem Inflammatory Syndrome. Kindly refer the details regarding Multisystem Inflammatory Syndrome from Centers for Disease Control and Prevention, USA at <u>https://www.cdc.gov/mis/</u>. Covishield does not contain SARS-CoV-2 virus and cannot cause Covid-19 infection. Also, Covishield is not known to cause multisystem inflammatory syndrome. However, we will continue to collect data for risk benefit analysis of the vaccine for vaccine safety.

## Representations by Petitioners to concerned authorities: Unanswered till date.

4. Petitioner No. 1 addressed a representation letter dated 14.7.2021 through the PMO portal to the Hon'ble Prime Minister of India (Registration No. : PMOPG/E/2021/0440276). It was allocated to an officer Satyendra Singh. There was no response received from the PMO office. Petitioner No.1 also sent a letter to ICMR to which also there was no reply received. She sent an email to Satyendra Singh in the PMO office requesting the status of her grievance complaint dated 14.7.2021, for which there was no reply. So Petitioner No.1 addressed another grievance dated 29.9.2021 to the Hon'ble Prime Minister of India (Registration No. : DHLTH/E/2021/17091) and to the Hon'ble Minister of Health and Family Welfare, Government of India. The said representation prayed for investigation into the unfortunate case of death of her 18 year old daughter due to adverse effect of Covid-19 vaccine. It also requested for accurate information on vaccine to be provided to people to ensure informed consent and decision making, usable and AEFI registration & transparent data, reports qua

discontinuation/restriction of Covidshield and voluntary administration of the vaccine along with disclosure and compensation for the families.

True copy of the Representation letter dated 29.9.2021 addressed by Petitioner No. 1 to Hon'ble Prime Minister and Hon'ble Minister of Health and Family Welfare, Government of India is attached herewith as Annexure P-1 at page no. 20 to 46. No reply has been received from any of the above mentioned departments.

5. Petitioner No. 2 first filed a petition through PMO portal (ref. PMOPG/E/2021/0442378) on 16.7.2021. It was seen allocated to an officer Sarita Nair. Petitioner No. 2 wrote emails to her and no response was received. Then the petitioner emailed to the District Collector of Coimbatore on 23.7.2021 and no reply received for that as well. Subsequently Petitioner No. 2 addressed a representation letter dated 1.10.2021 to the Hon'ble Prime Minister of India as well as Hon'ble Minister of Health and Family Welfare, Government of India. In the said representation Petitioner No. 2 has also mentioned that before this representation Petitioner No. 2 has raised his grievance before the appropriate authorities multiple times but no satisfactory response was received from their end. As a result of it, the said representation by Petitioner No. 2 also raised and requested similar reliefs from the appropriate authorities like accurate information on vaccine to be provided to people for informed consent and decision making, usable and transparent AEFI registration & data, reports qua discontinuation/restriction of Covidshield and voluntary administration of the vaccine along with disclosure and compensation for the families.

True copy of the Representation letter dated 1.10.2021 addressed by Petitioner No. 2 to Hon'ble Prime Minister and Hon'ble Minister of Health and Family Welfare, Government of India is attached herewith as **Annexure P-2 at page no.** <u>47 to 70</u>. No reply has been received yet for this representation also.

6. Thus the Petitioners No. 1 & 2 are filing this Writ Petition.

#### IN THE MATTER OF:

1. Rachana Gangu,

Aged about 44 years,

D/o G. Ranjit Narayan,

Hyderabad, Telangana- 500089.

2. Venugopalan Govindan,

Aged about 50 years,

S/o Govindan Gopalan,

...Petitioner No. 1

Vadavalli, Coimbatore, Tamil Nadu- 641041. ... Petitioner No. 2

Versus

1. Union of India,

Through its Secretary,

Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi- 110001. ....Respondent No. 1

 Central Drugs Standard Control Organization, Through the Drugs Controller General of India, FDA Bhavan, ITO, Kotla Road, New Delhi- 110002. ... Respondent No. 2

Indian Council of Medical Research,
 V. Ramalingaswami Bhawan, Ansari Nagar,
 New Delhi- 1100129. ....Respondent No. 3

Writ Petition under Article 32 of the Constitution of India seeking a writ, order or direction for appointment of an expert medical board, independent of the Government, to forthwith inquire into and investigate into the deaths of the daughters of Petitioners No. 1 & 2 and to share the report of the investigation with the Petitioners, as well as a writ, order or direction to the said expert medical board to prepare a protocol for early detection and timely treatment for the AEFI due to Covid-19 vaccine; and compensation to the Petitioners.

То

Hon'ble The Chief Justice of India and His Companion Justices of the Supreme Court of India

Humble petition of the Petitioners herein.

#### Most respectfully sheweth:

 The Petitioners No. 1 & 2 are compelled to file the present Writ Petition due to the untimely, tragic and avoidable demise of their 18 year and 20 year old daughters respectively. Petitioner No. 1's daughter received the first dose of the Covishield Covid-19 vaccine on 29.5.2021 and lost her life a few weeks later on 19.6.2021. Petitioner No. 2's daughter received the first dose of the Covishield Covid-19 vaccine on 8.6.2021 and lost her life a few weeks later on 10.7.2021. The Petitioners' respective daughters were healthy and bright young women with no known illnesses or physical disorders. Yet they started experiencing severe AEFI (Adverse Effects Following Immunization) soon after they received the vaccine shot. Petitioner No. 1's daughter suffered rapid decrease in her platelet count, incessant headache, vomiting and seizures, and physical, mental and emotional trauma, before she eventually lost her life while on life support, less than three weeks after she received the vaccine shot. Petitioner No. 2's daughter suffered from heightened immunomarkers and WBC, fever, trouble in throat, arthralgia, headache and myalgia, and exertional dyspnoea before she eventually lost her life. It is pertinent to note neither Petitioners nor their daughters were informed in advance of the risk of such severe AEFI and their informed consent was not taken before administering of the vaccine.

2. Having suffered the loss of their young daughters, the Petitioners are filing this Writ Petition seeking a writ, order or direction for appointment of an expert medical board, independent of the Government, to forthwith inquire into and investigate into the deaths of the daughters of Petitioners No. 1 & 2 and to share the report of the investigation with the Petitioners, as well as a writ, order or direction to the said expert medical board to prepare a protocol for early detection and timely treatment for the AEFI due to Covid-19 vaccine; and compensation to the Petitioners.

#### **Description of the Petitioners**

- 3. Petitioner no. 1 is currently a Homemaker. Her daughter Rithaika Sri Omtri, aged 18yrs, graduated from Class 12 and was pursuing to become a Civil Engineer. Rithaika was vaccinated with Covishield on 29.5.2021 and lost her life within 3 weeks on 19.6.2021.
- 4. Petitioner no.2 is an entrepreneur who runs Qualitime Software Private Limited, since 2002. His diseased daughter Karunya Venugopalan was pursuing 4<sup>th</sup> year M.Sc (Data Science) in PSG College of Technology and was interning with Goldman Sachs at the time of vaccination and her subsequent demise.
- 5. That the sequence of events leading to the present petition are as under:

Date	Particulars
29.5.2021	Petitioner No. 1's daughter administered Covishield
	vaccination on her left arm. After the vaccination she was
	advised to take paracetamol every six hours. After 2
	hours of administering Covishield vaccination, the
	Petitioner No. 1's daughter started complaining of
	headache and body pain. Furthermore, around 4.00 pm
	she started having a fever as well. In the late evening her
	fever did not subside and went up to 102.7 and after that
	she was given Paracetamol. Even after taking the
	prescribed medicine fever didn't come down to normal.

#### Brief facts relating to Petitioner No.1's Daughter

30.5.2021	Her fever didn't come down and she started to have
	severe body ache as well as headaches. Petitioner No. 1
	tried to follow the advice given at the vaccination center
	and started giving her daughter paracetamol every six to
	eight hours. As a result in order to reduce the fever the
	Petitioner No. 1's daughter took around three to four
	paracetamol in 2 days after vaccination.
30.5.2021-	Petitioner's daughter from the evening of 30.5.2021
4.6.2021	started feeling better till the next 5 days and was able to
	perform regular tasks and was living a normal life.
5.6.2021	However, on 5.6.2021 the Petitioner No. 1's daughter
	woke up around 3.30 am with a headache and started to
	scratch her head near the hairline of the head till the back.
	On the said night Petitioner No. 1's daughter could not
	sleep properly due to severe headache and woke up at
	about 12 noon. After she woke up, she also complained
	that her left thumb, and one of the small toes on her left
	foot were really sore and hurting. She was in extreme
	pain.
	Later in the day she started complaining about itching in
	her palms, and fingertips were tingly and numb. The
	Petitioner No. 1 booked an online doctor's appointment
	with Apollo 24/7 with Dr. Dhanraj K. K., who prescribed
	Avil (25mg) for allergic reaction and Calpol(650mg) for
	pain and advised that if symptoms do not get better within
	two days, the prescribed blood tests should be done.

6.6.2021	The symptoms subsisted and in addition she started
	complaining about burning pain in her hand and feet. Her
	palms were really hot and red.
7.6.2021	After two days of continuous suffering and no sign of
	relief, Petitioner No. 1 decided to take the blood tests
	advised by the Doctor during online consultation.
	Petitioner No. 1's daughter started to show even more
	symptoms such as pink spots underneath her palms and
	skins.
	Later around 8.50 pm, Vijaya Diagnostics, where
	Petitioner No. 1's daughter gave blood for testing, called
	and stated that her platelets were extremely low.
8.6.2021	It was confirmed by Vijaya Diagnostics that her platelets
	were really low at 40,000 only.
	Petitioner No. 1 booked another online doctor's
	appointment with Apollo 24/7 with Dr. Anish Anand.
	Upon learning about the new symptoms the said doctor
	suggested that it might be a viral infection like a bone and
	joint infection and told Petitioner not to worry and that
	Petitioner's No. 1's daughter seemed to be doing fine and
	advised them to go for a retest and few more tests
	including Dengue, the following day.
8.6.2021	Later at around 6 pm Petitioner No. 1's daughter started
	feeling extremely low with extreme headache, vomits,
	purple patch on her eyelid, dehydrated lips and due to no
	response from the online consultation app, Petitioner No.
	1 rushed her daughter in the night to the Emergency

	Room at Apollo Hospital, Film Nagar, Hyderabad.
	Petitioner No. 1's daughter was admitted and several tests
	were conducted on her and was referred to a neurologist
	asking for an MRI to be done.
	MRI could not be completed due to severe discomfort felt
	by Petitioner No. 1's daughter, however during the MRI
	process technician told Petitioner No. 1 that there must be
	a problem in the brain and her daughter needed to be
	admitted in the hospital.
9.6.2021	Around 6:30 am, a team of doctors who were looking
	after the case of Petitioner No. 1's daughter informed the
	Petitioner No. 1 that the Covid test was negative but
	platelets went down even further to 30,000 and
	incomplete MRI reports suggested that there seems to be
	problem in victim's brain hence immediate investigation
	should take place.
	After this the Petitioner No. 1's daughter was to be shifted
	into the ICU and meanwhile Petitioner No. 1's daughter
	got seizures. After a severe seizure she was put on a
	ventilator right away.
	Doctors confirmed via CT scan that she had blood clots
	in right frontal lobe of her brain which caused extensive
	hemorrhage and the pressure from the said hemorrhage is
	damaging her brain, and informed that they have to do an
	emergency surgery to release the brain pressure. As a
	result, a brain surgery called craniectomy was performed
	in order to release the brain pressure.

10 6 2021	
10.6.2021	Dr. Alok Ranjan, Neurosurgeon who performed the
	surgery on Petitioner No. 1's daughter informed
	Petitioner No. 1 that their daughter had been diagnosed
	with a condition called CVST-Cerebral Venous Sinus
	Thrombosis and also mentioned that her chances of
	survival were only 50%, and that even if she survived, her
	quality of life will be affected as her brain had been
	extensively damaged.
10.6.2021-	After the surgery, Petitioner No. 1's daughter was shifted
14.6.2021	to Neuro ICU and was under constant observation. Over
	six days after the surgery, several tests took place in order
	to get the proper treatment of Petitioner's daughter for the
	clots. In between the ongoing tests and to identify proper
	cause of the clots, Petitioner heard from the doctors that
	their daughter's condition was "Vaccine Induced
	Thrombotic Thrombocyopenia" (VITT) as they were
	unable to find any links to the present condition of
	Petitioner' daughter.
15.6.2021	Doctors informed Petitioner No. 1 that their daughter got
	some kind of shock and as a result of this the little pupil
	movement that she had after her brain surgery was also
	gone and there were no electrical signals or active brain
	stem activity in her brain and hence she was now
	completely dependent on ventilator. Thus she was
	declared brain dead by doctors. The doctors explained
	that this meant that she was clinically dead and there was
	no possibility that she was going to come back to life.

<b>F</b>	
	Thus, Petitioner No. 1 was given certain options such as
	to wait until rest of her daughter's body ceased to
	function and let her pass away, or that she could be shifted
	home, where the doctors would remove her life support
	and let her pass away as rest of her body stops to function,
	or they could donate her organs as her organs were still
	in perfect condition and could be donated to save
	someone else's lives.
15.6.2021-	Over the next 4 days Petitioner No. 1 researched about
19.6.2021	various other treatments looking for a way to save her
	daughter's life. However, nothing was in their favor as
	there were no signs of improvement as there was no blood
	flow from the neck onwards to the brain.
19.6.2021	The doctors informed Petitioner No. 1 that her daughter's
	brain was starting to degenerate and liquify and told her
	that it was unethical to continue to keep her daughter in
	that condition. In medical terms the doctor said that a
	person never comes back from brain dead and that the
	Petitioner No. 1 should decide about the next steps, as
	there was nothing left to be medically done to bring her
	back to life. Thus Petitioner No. 1 decided to donate the
	organs of her daughter and allowed the doctors to remove
	her life support and let her pass away.
20.6.2021	Autoney was done by a Drofassor from Osmania Madical
20.6.2021	Autopsy was done by a Professor from Osmania Medical
	College on behalf of the Government. The reports have
	still not been given to the Petitioner No. 1 even after

repeated requests by the Petitioner No. 1 as well as from
the hospital where her daughter was admitted.

# Brief facts relating to Petitioner No. 2's Daughter

Date	Particulars
8.6.2021	Petitioner No. 2's daughter was administered the
	Covishield vaccine and after vaccination she was
	experiencing tiredness, and had mild fever in the night.
17.6.2021	Petitioner's daughter started sensing trouble in throat and thus gargled with salt water. She went to bed with mild
	fever.
18.6.2021	Petitioner No. 2's daughter woke up with serious
	symptoms. She had high fever, along with severe throat
	pain, arthralgia, headache and myalgia
19.6.2021	An RTPCR test with Microbiological laboratories was
	conducted to test the for COVID-19. The test results
	came negative.
20.6.2021	The Petitioner No. 2's daughter was taken to Aroghya
	Nursing Home. The Doctor checked and gave her liquid
	medicines saying that her throat is very much inflamed
	and advised Petitioner No. 2 not to give his daughter
	anything solid to eat.
21.6.2021	Since there wasn't much improvement in her condition,
	the Petitioner No. 2's daughter was again taken to the
	hospital where the Doctor asked to admit her.

24.6.2021	Petitioner No. 2 via call reported the adverse effects to
	the Serum Institute of India (SII).
25.6.2021	As the treatment at Aroghya Nursing Home did not yield
	much result, and the severe difficulty in walking due to
	pain and the incessant fever continued, and the
	inflammatory markers continued to be high in blood
	tests, Petitioner No. 2's daughter was shifted to PSG
	Hospital, a speciality hospital with an attached Medical
	college. She also had exertional dyspnea by now. There
	were a variety of investigations including CT Scans,
	Echo, PET scans, etc. conducted apart from almost daily
	blood tests. The blood tests continuously gave
	heightened immunomarkers and WBC. She was put on a
	7 day antibiotics course.
4.7.2021	She was administered anticoagulants and steroids which
	gave her some relief. However the fever didn't go away
	and it was more pronounced in the night.
6.7.2021	At night she had fever with severe chills and shaking of
	whole body.
7.7.2021	Doctors began administering IV IgG. Unfortunately
	there was a sudden drop in her health on that afternoon,
	and her BP, pulse, O2 level all started dropping
	alarmingly. She was put on O2, and was rushed to the
	ICU. From there it was downhill and she never
	recovered.
10.7.2021	Petitioner No. 2's daughter passed away.
22.7.2021	In response to a series of emails written by the Petitioner
	No. 2, Dr. Sumit Tandon, Senior Manager, Clinical
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Research and Pharmacovigilance Dept., Serum Institute of India Pvt. Ltd., 212/2, Hadapsar, Pune - 411 028, <sumit.tandon@seruminstitute.com>, wrote: Dear Mr Venugopalan, Thanks for sharing all the reports. Currently, Covid-19 infection is considered as the cause of Multisystem Inflammatory Syndrome. Kindly refer the details regarding Multisystem Inflammatory Syndrome from Centers for Disease Control and Prevention, USA at https://www.cdc.gov/mis/. Covishield does not contain SARS-CoV-2 virus and cannot cause Covid-19 infection. Also, Covishield is not known to cause multisystem inflammatory syndrome. However, we will continue to collect data for risk benefit analysis of the vaccine for vaccine safety.

## Representations by Petitioners to concerned authorities: Unanswered till date.

6. Petitioner No. 1 addressed a representation letter dated 14.7.2021 through the PMO portal to the Hon'ble Prime Minister of India (Registration No. : PMOPG/E/2021/0440276). It was allocated to an officer Satyendra Singh. There was no response received from the PMO office. Petitioner No.1 also sent a letter to ICMR to which also there was no reply received. She sent an email to Satyendra Singh in the PMO office requesting the status of her grievance complaint dated 14.7.2021, for which there was no reply. So Petitioner No.1 addressed another grievance dated 29.9.2021 to the Hon'ble Prime Minister of India (Registration No. : DHLTH/E/2021/17091) and to the Hon'ble Minister of Health and Family Welfare, Government of India. The said

representation prayed for investigation into the unfortunate case of death of her 18 year old daughter due to adverse effect of Covid-19 vaccine. It also requested for accurate information on vaccine to be provided to people to ensure informed consent and decision making, usable and transparent AEFI registration & data, reports qua discontinuation/restriction of Covidshield and voluntary administration of the vaccine along with disclosure and compensation for the families.

True copy of the Representation letter dated 29.9.2021 addressed by Petitioner No. 1 to Hon'ble Prime Minister and Hon'ble Minister of Health and Family Welfare, Government of India is attached herewith as Annexure P-1 at page no. 20 to 46. No reply has been received from any of the above mentioned departments.

7. Petitioner No. 2 first filed a petition through PMO portal (ref. PMOPG/E/2021/0442378) on 16.7.2021. It was seen allocated to an officer Sarita Nair. Petitioner No. 2 wrote emails to her and no response was received. Then the petitioner emailed to the District Collector of Coimbatore on 23.7.2021 and no reply received for that as well. Subsequently Petitioner No. 2 addressed a representation letter dated 1.10.2021 to the Hon'ble Prime Minister of India as well as Hon'ble Minister of Health and Family Welfare, Government of India. In the said representation Petitioner No. 2 has also mentioned that before this representation Petitioner No. 2 has raised his grievance before the appropriate authorities multiple times but no satisfactory response was received from their end. As a result of it, the said representation by Petitioner No. 2 also raised and requested similar reliefs from the appropriate authorities like accurate information on vaccine to be provided to people for informed consent and decision making, usable

and transparent AEFI registration & data, reports qua discontinuation/restriction of Covidshield and voluntary administration of the vaccine along with disclosure and compensation for the families.

True copy of the Representation letter dated 1.10.2021 addressed by Petitioner No. 2 to Hon'ble Prime Minister and Hon'ble Minister of Health and Family Welfare, Government of India is attached herewith as Annexure P-2 at page no. 47 to 70. No reply has been received yet for this representation also.

#### GROUNDS

- 8. Hence the Petitioners No. 1 & 2 move this Hon'ble Court by way of this petition on, inter alia, the following grounds:
  - A. BECAUSE, the Government has not prepared any protocol for early detection and timely treatment for the AEFI due to the Covid-19 vaccine such as the ones that led to the deaths of the daughters of Petitioners No. 1 & 2;
  - B. BECAUSE, the Government has not shared with Petitioner No. 1 the autopsy report prepared after her daughter's death.
  - C. BECAUSE, Petitioners No. 1 & 2 have addressed repeated representations to the Government, but there has been no reply from the Government.

- D. BECAUSE, Petitioners No. 1 & 2 and their daughters were not informed of the possible severe AEFI before they were administered the Covid-19 vaccine.
- E. BECAUSE, the informed consent of the Petitioners No. 1 & 2 and their daughters was not taken before administering of the Covid-19 vaccine.
- That the Petitioners have not filed similar petition before this Hon'ble Court or before any other Court for similar reliefs prayed by the Petitioner herein.
- 10. That the Petitioners crave leave of this Hon'ble Court to file additional affidavits at a later stage if so advised.
- 11. That the present petition is made bonafide and for the ends of justice.

#### PRAYERS

- 12.In the abovementioned facts and circumstances, it is most respectfully prayed that this Hon'ble Court may be pleased to:
  - 1. Issue a writ of mandamus or any other appropriate writ, order or direction appointing an expert medical board, independent of the Government, to forthwith inquire into and investigate into the deaths of the daughters of Petitioners No. 1 & 2, and to share the report of the autopsy and investigation with the Petitioners in a time-bound manner;

- 2. Issue a writ of mandamus or any other appropriate writ, order or direction directing the above appointed expert medical board to prepare a protocol for early detection of and timely treatment for the AEFI due to the Covid-19 vaccine such as the ones that led to the deaths of the daughters of Petitioners No. 1 & 2; and
- 3. Issue a writ of mandamus or any other appropriate writ, order or direction directing the Respondents to grant significant monetary compensation to the Petitioners No. 1 & 2, which will be donated by the Petitioners to organizations working on social issues.

## AND FOR THIS ACT OF KINDNESS, YOUR HUMBLE PETITIONERS AS IS DUTY BOUND SHALL EVER PRAY

Petitioner Through

Smf.

AOR for petitioner (s)/ appellant(s) (Name): Mr. Satya Mitra Registration No. 1852 <u>satyamitra2003@gmail.com</u>

Filed On:

#### **IN THE MATTER OF:**

Rachana Gangu & Anr.

...Petitioners

Union of India & Ors.

...Respondents

#### Affidavit

Versus

I, Rachana Gangu, Aged about 44 years, D/o G. Ranjit Narayan, , do

hereby solemnly affirm and declare on oath asunder:

- 1. That I am the Petitioner No. 1 in the abovenamed Petition. I am well conversant with the facts and circumstances of the case and hence competent to swear this Affidavit on behalf of both Petitioners No. 1 & 2.
- I have read the contents of the synopsis and list of dates on pages B-<u>M</u>, as well as the contents of the petition in paragraph 1-<u>8</u> at pages 1-<u>18</u> and accompanying applications as shown and explained to me in vernacular. I have understood the contents thereof.

- 3. That the Annexures annexed with this Writ Petition are true copies of their respective originals.
- 4. This Writ Petition is being filed under my instructions and the contents thereof are true to the best of my knowledge and belief and nothing material has been concealed

DEPONENT

#### **VERIFICA TION:**

Verified at New Delhi on this day the <u>27</u> of <u>October</u>, 2021 that the contents of the above affidavit are true and correct to the best of my knowledge, that no part of it is false and nothing material has been concealed therefrom.

DEPONENT

#### APPENDIX

# **Constitution of India, 1950**

Article 21. Protection of life and personal liberty: No person shall be deprived of his life or personal liberty except according to procedure established by law

# Annexure P-1

Date: 29.9.21

To,

Shri Narendra Modi, The Hon'ble Prime Minister of India, New Delhi

Shri Mansukh Mandaviya, The Hon'ble Union Minister, Ministry of Health and Family Welfare, New Delhi Email: <u>hfm@gov.in</u>

Dear Sir,

## Subject: Urgent request to investigate the Serious Adverse Event

## Following Immunization of our Daughter, Rithaika (age 18 years).

I write to you with a heavy heart to inform you of the untimely, tragic and

avoidable demise of my 18-year old daughter, Rithaika Omtri, following Covid-19

vaccination. We have communicated the same to you as per the following

details:

- a. Via Portal: Details for registration number: <u>PMOPG/E/2021/0440276</u> Name of Complainant: Rachana Gangu Date of Receipt: 14/7/21 Officer Concerns To Officer Name: Satyendra Singh Officer Designation: Under Secretary Email Address: singh.satyendra80@gov.in
- b. Via Email: From: Rachana Gangu

Date: Fri, Jul 16, 2021 at 4:59 PM Subject: Adverse reaction to Covishield - Passing of an 18yr old To: <u>r.attri54@nic.in</u> Cc: <secy-dg@icmr.gov.in>, <samiranpanda.hq@icmr.gov.in>, <<u>anjusharma.hq@icmr.gov.in</u>>

 c. Via Email: From: Rachana Gangu Date: Tue, Sep 28, 2021 at 10:49 AM Subject: Requesting the status of the Grievance Complant To: <singh.satyendra80@gov.in>

However, there was no response from your office.

I would like to once again brief you on the matter of our case. Rithaika, our daughter, had received the first dose of the Covishield Covid-19 vaccine on 29.5.2021, and lost her life a few weeks later on 19.6.2021. She was a healthy and bright young woman with no known illnesses or physical disorders. Yet she started experiencing severe AEFI (Adverse Effects Following Immunization) soon after she received the vaccine shot. She suffered rapid decrease in her platelet count, incessant vomiting and seizures, and physical, mental and emotional trauma, before she eventually lost her life while on life support, less than three weeks after she received the vaccine shot.

Having suffered the loss of our young daughter, we would like to urge you to direct the appropriate authorities to actively follow up to record and investigate

instances of deaths/serious adverse events following immunization, to advertise extensively in newspaper, television, radio (during prime time) and on social media that any person dying or suffering serious adverse events of vaccination may complain directly to officials and to further direct the authorities to mandatorily record all the cases being reported, and to frame extensive programme for the payment of substantial compensation for those dying or experiencing serious adverse events within 30 days of vaccination.

Please find below the facts of our case for your reference.

Date	Particulars
Date	
29.5.2021	Our daughter was administered Covishield vaccination on her
	left arm.
	After the vaccination, we were given 4 paracetamol tablets and
	were advised to take it every six hours.
29.5.2021	After 2 hours of administering Covishield vaccination, our
	daughter started complaining about headache and body pain.
	Furthermore, around 4.00 pm she started having a fever as
	well.
29.5.2021	Same day in the late evening after administering the vaccine our
	daughter's fever did not subside and went up to 102.7 and after

	that she was given Paracetamol. Even after taking the
	prescribed medicine, the fever didn't come down to normal.
30.5.2021	Next day after taking the vaccination, her fever didn't come
	down and she started to have severe body aches as well as
	headaches. We tried to follow the advice given at the
	vaccination center and started taking paracetamol every six to
	eight hours. As a result in order to subside the fever our
	daughter took around three to four paracetamol in 2 days after
	vaccination.
30.5.2021-	Rithaika, from the evening of 30.5.2021, started feeling better
4.6.2021	till the next 5 days and was able to perform regular tasks and
	was living a normal life.
5.6.2021	However, on the said date around 3.30 am she woke up with a
	headache and started to scratch her head near the hairline of
	the head till the back. On the said night, she could not sleep
	properly due to severe headache and woke up at about 12.00 or
	12.30 pm. After she woke up she mentioned that her left thumb
	was really sore and was hurting. Also, one of the small toes on
	her left foot was also hurting and she was in extreme pain.

5.6.2021	Our daughter also later in the day started complaining about
	itching in her palms, and fingertips were tingly and numb. As a
	result of this online doctor's appointment with Apollo 24/7 with
	Dr. Dhanraj K.K was booked and after online consultation
	considering her symptoms, the doctor advised Avil (25mg) for
	allergic reaction and Calpol (650mg) for pain and advised that if
	symptoms do not get better within 2 two days, he prescribed
	blood tests to be done.
6.6.2021	There were no signs of symptoms subsiding but our daughter in
	addition complained about burning pain in her hand and feet. As
	her palms were really hot and red.
7.6.2021	Upon two days of continuous suffering and no sign of relief we
	decided to take the blood tests advised by the Doctor via online
	consultation. Addition to ongoing suffering she started to show
	even more symptoms such as pink spots underneath her palms
	and skin.
	On the same day around 8.50 pm in the night Vijaya
	Diagnostics, where she gave blood for testing, called and stated
	that her platelets were extremely low.

platelets were real	y low at 40,000 only.
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As a result of no proper diagnosis and continuous suffering we booked another online doctor's appointment with Apollo 24/7 with Dr. Anish Anand.

Upon learning new symptoms the said doctor suggested that it might be a viral infection like a bone and joint infection and told us not to worry and that she seemed to be doing fine and advised us to go for a retest and few more tests including Dengue, the following day .

8.6.2021	In the evening around 6.00 pm Rithaika started feeling
	extremely low with extreme headache, vomits , purple patch on
	her eyelid, dehydrated lips and due to no response from the
	online consultation app, we rushed our daughter in the night in
	the emergency room of the Apollo hospital, Film Nagar,
	Hyderabad. She was admitted and several tests were conducted
	on her and was referred to a neurologist asking for an MRI to be
	done.
8.6.2021	MRI could not be completed due to severe discomfort felt by our
	daughter, however during the MRI process the technician told us
	that there must be a problem in the brain of the victim and she

	we and the last substitute of the last substitute in the second second
	needs to be admitted into the hospital.
9.6.2021	On the said date around 6.30 am early in the morning, team of
	doctors who were looking after the case of our daughter
	informed us that after looking at all the blood reports Covid test
	is negative but platelets went down even further to 30,000 and
	incomplete MRI reports suggested that there seems to be
	problem in victim's brain hence immediate investigation should
	take place.
	After which she was admitted and was to be shifted in ICU
	looking at her condition and meanwhile she got seizures. After a
	severe seizure she was put on a ventilator right away.
9.6.2021	Doctors confirmed via CT scan that she has blood clots in right
	frontal lobe of her brain which caused extensive hemorrhage
	and the pressure from the said hemorrhage is damaging her
	brain, and informed that they have to do an emergency surgery
	to release the brain pressure. As a result, a brain surgery called
	craniectomy was performed in order to release the brain
	pressure.
10.6.2021	Doctor Alok Ranjan, Neurosurgeon who operated Rithaika's
	surgery, informed us that our daughter has been diagnosed with

	condition called CVST-Cerebral Venous Sinus Thrombosis and
	also mentioned that her chances of survival is only 50% and
	even if she survived her quality of life will be affected as her
	brain has been extensively damaged.
9.6.2021-	After the surgery she was shifted to Neuro ICU and was under
14.6.2021	constant observation. Over six days after the surgery, several
	tests took place in order to get the proper treatment of hers for
	the clots. In between the ongoing tests and to identify proper
	cause of the clots, we heard from the doctors that our
	daughter's condition could also be "Vaccine Induced
	Thrombotic Thrombocyopenia" (VITT) as they were unable
	to find any links to the present condition of our daughter.
15.6.2021	Doctors informed the us that our daughter got some kind of
	shock and as a result of which little pupil movement she had
	after her brain surgery was also gone and there were no
	electrical signals or active brain stem activity in her brain hence
	she was now completely dependent on ventilator and was
	declared brain dead by doctors. They explained that since she
	was brain dead, which meant she was clinically dead and there
	was no way, she was going to get back to life. Thus, we were

given certain options like to wait until rest of her body ceases to function and let her pass away, or she can be shifted home, remove her life support and let her pass away as rest of her body stops to function, or they can donate her organs as her organs were still in perfect condition which could be donated to save someone else's lives.

15.6.2021- Over the next 4 days we tried various other treatments and 19.6.2021 researched several treatments in order to come up with something to get our daughter treated. However, there were no signs of improvement as there was absolutely no blood flow from the neck onwards to the brain.

19.6.2021 The doctors informed us that her brain was starting to degenerate and liquify and told us that it was unethical to continue to keep her in that condition. In medical terms the doctor said that a person never comes back from brain dead and that we should decide about the next steps, as there was nothing left to be medically done to bring her back to life. We decided to donate organs of our daughter and allowed to remove her life support and let her pass away.

20.6.2021 Autopsy was done by the Professor from Osmania Medical

College from the Government and reports are still not given to us even after repeated requests by us as well as from the hospital where she was admitted.

After the passing of our daughter, we were compelled to do our own research regarding the Covid-19 vaccines and especially Covishield (Astrazeneca) vaccine. It was shocking to find out that Covishield vaccine is banned or age-restricted in 14 countries. There is a clear link between blood clots and Covishield vaccine, especially experienced by young people. We are deeply pained that this information was not available to us before we decided to take the vaccine.

Please find below some references of our research:

1. <u>https://www.cityam.com/why-have-almost-half-eu-countries-restricted-use-of-</u> <u>the-astrazeneca-vaccine/</u>

2. <u>https://www.wionews.com/world/spain-puts-maximum-age-limit-for-</u> receiving-astrazeneca-vaccine-361744

3. <u>https://7news.com.au/lifestyle/health-wellbeing/astrazeneca-likely-to-be-</u> phased-out-as-australias-covid-vaccine-forecast-is-revealed-c-3205325

4. https://www.bbc.com/news/world-australia-57549796

We are also very disappointed with the AEFI reporting & monitoring mechanisms. All the authorities were reluctant to call the experience of our daughter an adverse event due to the vaccine. The state authorities responsible for the AEFI investigation have refused to give us any details of the case. We are deeply saddened to see various states, public and private institutions and companies mandating these experimental vaccines. When these vaccines have a potential risk of death, it must be left to the individual to decide whether they wish to take the risk or not.

In view of the above mentioned facts and circumstances, we seek the following relief from your Office:

# Accurate information on Vaccines to be provided to the people for

#### informed consent and decision making

1. We request the authorities administering the Covid vaccine drive to provide the following:

a. Fact sheets or vaccine inserts to be provided to each vaccine recipient at the time of registration (through Cowin, whatsapp or walk-in). The fact sheet to include the list of ingredients, possible allergic reactions, risk of mild, moderate and severe life threatening side effects like blood clots leading to death. This information needs to be also PROMINENTLY displayed at all vaccination sites.

b. Blood clots occurring in the brain, heart, etc. in certain people,
 especially young girls/women, should be listed as an Adverse Event for
 Covid Vaccines as part of the informed consent.

c. All advertisements, ringtones, TV commercials should stop making misleading claims of safety such as 'vaccines manufactured in India are **completely safe'**. The advertisements should include without fail information on possible adverse effects in some like blood clotting, which could be fatal.

2. Each citizen receiving the vaccination be given guidance as to the early signs of adverse reactions and recommended certain precautionary tests leading to early detection. If caught early, appropriate timely tests and treatment can save lives.

3. Those not eligible for the covid vaccination due to allergies and/or certain health conditions be assessed for the same and informed as such.

4. Protocols to identify and treat blood clots post vaccination, to be provided to the medical fraternity.

#### Usable and transparent AEFI registration & data

5. That the Government is requested to enable the following:

a. To be able to register adverse events after vaccination through COWIN portal and once an adverse event is registered by a vaccine recipient (or relatives in case of deaths or v. serious adverse event), he/she should be able to track the status of his/her report through the portal. The AEFIs registered should be examined and rulings passed on them on a timebound manner such as 2-3 weeks for any deaths reported, and 4-6 weeks for adverse events requiring hospitalisation etc.

b. To be able to register adverse events after vaccination through Toll Free Number - 1075 and once an adverse event is registered by a vaccine recipient (or relatives in case of deaths or v. serious adverse event), he/she should be able to track the status of his/her report through the same number.

c. To be able to register adverse events after vaccination through Whatsapp Number - 9013151515 and once an adverse event is registered by a vaccine recipient (or relatives in case of deaths or v. serious adverse event), he/she should be able to track the status of his/her report through the same whatsapp chat.

d. The Adverse events data (without identifying victims) should be transparently accessible in COWIN portal and in <u>www.cowin.gov.in</u> for public use.

e. The entire process of AEFI be kept transparent to the victim's family, and provide a status of the case when requested by the family. As currently the victim's family has no way of knowing the status of an AEFI case and are kept completely uninformed.

#### **Reports qua Discontinuation/Restriction of Covishield**

6. That the Government is requested to phase out or at least age limit the use of COVISHIELD in younger population. COVISHIELD (known as astrazeneca vaccine globally) is

- a. Not approved for use in many countries (USA, Switzerland, Denmark...)
- b. Age-limited for use in many countries (Italy, Germany, France ..)
- c. Being phased out in Australia

This is to be done at the earliest to prevent any loss of lives or serious adverse effects that are happening with massive vaccination drives.

#### Voluntary administration of the Vaccine

7. For an order directing all authorities and private parties to follow the Union of India's decision to make the administration of vaccine purely voluntary. There should be no denial of services like entry to education institutions, public places etc based on non-vaccinated status of an individual.

#### Disclosure

8. For an order directing the respondents to publicly disclose the following information as sought for by 24 eminent health rights experts by letters dated
 31.01.2021 (at Annexure 1) and 16.03.2021 (at Annexure 2) asunder:

a. Full details of the committees that conducted the investigation and causal assessment including the procedure followed, the findings and the basis on which conclusions were arrived at as to whether the deaths were related to the vaccine or not.

b. Complete information on all deaths, severe and serious AEFI's in the vaccine rollout.

c. Full details of the affiliations and the qualifications of all AEFI investigation committee members including any group of experts overseeing the vaccine rollout.

d. The minutes of all the investigation committee meetings.

#### Compensation

9. That the authorities be directed to frame and publish an extensive programme for the payment of substantial compensation for those dying or experiencing serious adverse events of vaccination where the deaths and serious adverse events are very likely/certainly, probably, possibly a result of the vaccine in accordance with the Brighton Criteria as accepted in the "Adverse Events Following Immunization (AEFI): Causality Assessment" published by WHO in 2005. This must be definitely done for those victims who were the bread winners of their family.

We look forward to a positive response from you. We hope to see your office take positive measures to address our aforementioned prayers.

With Warm Regards,

Rachana Gangu & Pavan Omtri

#### Annexure 1

# **URGENT ATTENTION**

Date: 31 January 2021

## 1. Hon'ble Dr. Harsh Vardhan

Union Minister Ministry of Health and Family Welfare, New Delhi Email: hfm@gov.in

#### 2. Dr. V. G. Somani

Drugs Controller General of India New Delhi Email: dci@nic.in

#### 3. Dr. V. K. Paul

Member, NITI Aayog Chair, National Expert Group on Vaccine Administration For COVID-19 Email: vinodk.paul@gov.in; vinodkpaul@gmail.com

 Dr. Renu Swarup Secretary, Department of Biotechnology Chair, NTAGI Email: secy@dbt.nic.in

# **Subject:** Investigations of deaths of 11 healthcare and frontline workers following administration of COVID-19 vaccine

Dear Sir(s) and Madam,

We write to you with the trust that you will take cognizance of our concerns and respond promptly. We refer to the deaths of eleven health and frontline workers between 16 and 30 January, 2021, following administration of the COVID-19 vaccine, as reported in the media. The deaths took place in the States of Uttar Pradesh, Karnataka, Andhra Pradesh, Rajasthan, Telangana, Gurugram, Odisha, and Kerala.

The 11 deaths, reported in the media, took place between a few hours and five days of persons (primarily 42 to 56 years old) healthcare workers, and a frontline worker (23 years old), taking the vaccines, and all have been ascribed to cardiovascular problems or "brain stroke". The vaccine taken in each case was Covishield.

Though the district/state officials have stated that none of the deaths are related to the vaccine, the reports of the District, State and National AEFI Committees on the assessment of these deaths and other serious AEFIs have not been released. No details of who investigated the deaths, and the methodology used for each investigation, have been made public. The National Committee has an obligation to investigate possible patterns in causative factors for these deaths.

We would like to bring to your notice that the 11 deaths meet the WHO's definition of a "**cluster" of serious AEFIs** as given in its *Covid-19 vaccines: safety surveillance manual --* "when two or more AEFIs related in time, place or by vaccine occur" (1). Guidelines for investigation of cluster AEFIs are given in the WHO's global manual for surveillance of adverse events following immunization (2). AEFIs must be investigated urgently in order to issue warnings to people who should not take it due to contraindications, to correct errors, to reassure the public, as well as to identify potential serious problems in the vaccine. The algorithm for cluster AEFI investigation can rule out errors in manufacturing or administration, anxiety clusters, and coincidental events, *to identify signals for further investigation*.

The health and frontline workers who died had volunteered to take the vaccine with the trust in your decision to give emergency approval to the vaccine to protect them from a serious disease. They are owed some respect and dignity, and they have a right to at least a prompt, thorough and transparent investigation of their deaths, and action based on that investigation.

We strongly urge you to provide the following information and place it in the public domain:-

- 1. *Has an investigation into the 11 deaths taken place?* Please give details of the committees that conducted the investigation and causal assessment. What procedure did the investigations follow, what were the findings, and on what basis was it concluded that the deaths were not related to the vaccine?
- 2. Have there been any other reports of deaths or other severe or serious AEFIs following administering of the covid19 vaccine? Please place complete information on **all deaths, severe and serious AEFIs** in the COVID-19 vaccine rollout, and their investigation, in the public domain. This information should include the numbers, date of vaccination, details of the AEFI, place, investigation status and results. Please also release the minutes of the National, State and District AEFI Committees.

- 3. Why are the names, affiliations and qualifications of all AEFI investigation committee members at the District, State and Central level not in the public domain? Please make the names and affiliations of Committee Members public.
- 4. *Is there any group of experts overseeing the vaccine rollout?* Please make their names, expertise and affiliations public.
- 5. Has any committee of experts discussed whether the vaccine rollout should be paused pending final investigation and determination in the deaths and other serious AEFIs reported? Please release the minutes of the committee meetings where such discussions took place, with the explanation for not temporarily pausing vaccination.
- 6. *Will the programme be amended based on deaths, serious AEFIs investigation findings?* Will the programme be re-assessed and amended, with warnings, informed consent, etc., prior to the completion of the rollout of the first dose and prior to the commencement of the rollout of the second dose of the vaccine?
- 7. Will any no-fault compensation be paid to the families of the healthcare and *frontline workers who died?* This is all the more important because the COVID-19 vaccines are not *fully approved* but only given emergency use approval with limited data.

We request you to kindly acknowledge this letter and to respond promptly to our queries and concerns. We hope you will take steps in the right direction so as to ensure that trust, transparency, and honesty is inculcated and maintained in the vaccine rollout programme.

#### Regards,

Ms Sandhya Srinivasan, Consulting Editor, *Indian Journal of Medical Ethics*, Mumbai Dr Amar Jesani, Editor, *Indian Journal of Medical Ethics*, Mumbai Adv Veena Johari, Advocate, Courtyard Attorneys, Mumbai Dr Antony R Kollanur, Consultant Public Health, Kochi Dr Babu KV, Public Health Activist, Kerala Dr Chayanika Shah, PhD, Queer Feminist Activist and Science Studies Researcher, Mumbai Mr Chinu Srinivasan, Low Cost Standard Therapeutics (LOCOST), Vadodara Dr George Thomas, Orthopaedic Surgeon, Chennai Dr Imrana Qadeer, Former Professor, Centre of Social Medicine and Community Health, JNU, New Delhi Ms Laxmi Murthy, Journalist, Bangalore Ms Malini Aisola, Public Health Researcher, Delhi Dr Mira Shiva, Co-convenor, All India Drug Action Network, Delhi **Dr Mohan Rao**, Former Professor, Centre of Social Medicine and Community Health, JNU, New Delhi

Dr Prabir Chatterjee, Independent Public Health Consultant, Bankura

Dr Ramani Akturi, Independent Public Health Physician, Bhopal

Dr Ravi Dsouza, Community Health Physician, Bhopal

Dr Sanjay A Pai, Working Editor, Indian Journal of Medical Ethics, Bangalore

**Dr Sanjay Nagral**, Director, Department of Surgical Gastroenterology, Jaslok Hospital and Research Centre, Mumbai

Dr Sejal Tambat, Family Medicine Practitioner, Mumbai

Dr SP Kalantri, Physician, Sewagram

Dr Sylvia Karpagam, Public Health Doctor and Researcher, Bangalore

Dr T Jacob John, Retired Professor and Head, Department of Clinical Virology,

Christian Medical College, Vellore

Dr Vandana Prasad, Public Health Professional, Delhi

# Cc:

1. **Mr. Rajesh Bhushan**, Secretary, MOHFW, Co-Chair National Expert Group on Vaccine Administration for COVID-19: email: secyhfw@nic.in

2. Dr. S Eswara Reddy, Joint Drugs Controller: email: se.reddy@nic.in

3. Dr. PBN Prasad, Joint Drugs Controller: email: pbn.prasad@cdsco.nic.in

4. **Dr. Balram Bhargava**, Director General ICMR, & Vice Chair NTAGI: email: secy-dg@icmr.gov.in

5. Dr. Pradeep Haldar, Deputy Commissioner (Imm.I/C): email:

pradeephaldar@yahoo.co.in

6. Dr. M K Aggarwal, Deputy Commissioner (UIP): email: drmkagarwal2@gmail.com

7. Mr. A K Pradhan, DDC(I), CDSCO: email: akpradhan@cdsco.nic.in

8. **Dr. Roderico Ofrin**, Regional Emergencies Director, Office of the WHO Representative India: email: wrindia@who.int

9. **Dr. J N Shrivastava**, Executive Director, NHSRC, Chairman National Quality Assurance Committee for AEFI Surveillance Program; email: nhsrcindia@gmail.com 10. **Mr. P K Mishra**, Principal Secretary, PMO: email: pkmishra.pmo@gov.in

# References

- Covid-19 vaccines: safety surveillance manual. Geneva: World Health Organization; 2020. P. 63. Available from: https://www.who.int/publications/i/item/10665338400
- 2. *Global manual on surveillance of adverse events following immunization*. Geneva: World Health Organization; 2014 (Revised March 2016). P. 58. Available from:

https://www.who.int/vaccine\_safety/publications/Global\_Manual\_revised\_12102 015.pdf?ua=1

Annexure 2

Date: 16 March 2021

1. Hon'ble Dr Harsh Vardhan Union Minister Ministry of Health and Family Welfare New Delhi Email: <u>hfm@gov.in</u>

2. Dr VG Somani Drugs Controller General of India New Delhi Email: <u>dci@nic.in</u>

3. Dr VK Paul Member, NITI Aayog Chair, National Expert Group on Vaccine Administration For COVID-19 Email: vinodk.paul@gov.in; <u>vinodkpaul@gmail.com</u>

4. Dr Renu Swarup Secretary, Department of Biotechnology Chair, NTAGI Email: <u>secy@dbt.nic.in</u>

5. Dr NK Arora Member, National Task Force on COVID-19 Advisor, National AEFI Committee, Delhi Email: nkarora@inclentrust.org; narendrakumararora@gmail.com

Urgent investigation of deaths and serious adverse events following administration of COVID-19 vaccine

We are writing to you as people working in public health, ethics, medicine, law, and journalism, and as members of the public, who support the immunisation programme. We wrote to you earlier on 31 January 2021 expressing our concerns regarding the lack of information on the investigations of deaths following COVID-19 vaccination in India. We are disappointed at the

government's silence on our letter while further reports of deaths following administration of COVID-19 vaccine are appearing in the media.

The government is responsible for ensuring safety of all vaccines and particularly those administered through a government programme. This includes monitoring and surveillance of adverse events following immunisation (AEFIs). AEFIs are to be investigated through well-defined procedures for vaccine pharmacovigilance and the reports made available in the public domain, for trust-building and transparency. This is especially important for new vaccines such as the COVID-19 vaccines currently being rolled out across the country under emergency use authorisation, targeted to millions of people.

We understand that at least 65 deaths have occurred following vaccination for COVID-19 since the vaccination campaign started on January 16. However, the National AEFI Committee's investigation findings of only two of these deaths have been made public.

Till now, no case of serious AEFI including death has been attributed to the vaccine. Denmark, Iceland, Norway, Italy, France, Bulgaria, Germany, Luxembourg, Estonia, Lithuania, Latvia and Ireland have paused immunisation with the Astra Zeneca vaccine pending investigation of a small number of post-vaccination deaths from intravascular clotting/ thromboembolic events, while Austria has suspended the use of certain batches.

Media reports indicate that many deaths post vaccination with COVISHIELD, AstraZeneca's vaccine which is being manufactured in India by the Serum Institute of India, occurred due to cardiac arrest, cerebral venous thrombosis and stroke.

We believe that due to the possible linkages of vaccination and blood clotting, all these deaths and adverse events should be reviewed together for a possible causal relationship with the vaccine. We raise one possibility: human cells bearing SARS-CoV-2 spikes displayed on the surface, are, for the ACE 2 receptors, like the virus itself. The event cascade leading to clotting is a part of the pathogenesis of the virus-human interactions. We suggest that there is a possibility of this being enacted by some vaccines.

Reports of other serious AEFIs including neurological symptoms, hemiplegia and Guillain-Barre syndrome also need to be investigated. As the vaccination drive has been expanded to include persons over 60 years and persons above 45

years with specified morbidities, it is all the more important to investigate any possibilities of the COVID-19 vaccines triggering serious AEFI in people with certain medical conditions, who are the very people in need of vaccination. Could they be 'predisposed' to aggravation of their basic condition?

We note with concern that critical updates to the fact sheets recommended by the CDSCO's Subject Expert Committee have not been issued, even though they are meant to provide additional guidance and clarify use of the vaccines in persons such as those with allergies, who are immunocompromised or using immunosuppressants, or using blood thinners/anti-coagulants.

There are gaps in AEFI investigations at the local level, affecting the quality of evidence submitted to State and National AEFI Committees who depend on these findings for making causality assessments. The National AEFI Committee also has a critical role in assessing cases that present as a cluster and to explore potential common pathways.

In our letter dated January 31, 2021, we asked for details of all investigations into deaths and other serious AEFIs, as well as the minutes of AEFI monitoring committees, and details of all AEFI committee members and other experts overseeing the vaccine rollout. We have not received any response. We also note that the government has stopped sharing any details of AEFIs after February 26, 2021.

Lakhs of people in India are being administered the COVID-19 vaccines every day in the confidence that the vaccine will protect them against severe disease and death. The vaccine programme owes them complete information on the vaccines, a vaccination protocol that minimises the risk of harm, and an assurance of thorough and transparent investigation of injuries and death following immunisation. They are also owed medical care, and compensation for harm suffered post vaccination. The government has not met these obligations.

The government must immediately undertake complete, time-bound and transparent investigation of all deaths and other serious adverse events following vaccination with the COVID-19 vaccine.

The following must be put in the public domain: 1. For each of the vaccines rolled out, details of all serious AEFIs as of March 16, 2021, and the status of investigation; 2. Findings of all completed serious AEFI investigations, including:

a. cause of death by clinical diagnosis;

b. autopsy findings when possible, or verbal autopsy, to confirm or revise the clinical diagnosis;

c. causality assessment and the reasoning behind that assessment;

d. aetiology; if no aetiology is found, the death must provisionally be attributed to the vaccine, and

e. the process undertaken by the various AEFI committees, including whether the WHO guidelines for investigation of AEFI occurring as cluster have been strictly followed,

f. cause of other AEFIs, and the causality assessments by the various committees.

Based on the findings of investigations the vaccination protocols should be modified with screening procedures that decrease the probability of serious adverse events following immunisation, if found necessary.

Awaiting a response,

Thanking you,

Sincerely,

**Ms Sandhya Srinivasan**, Consulting Editor, Indian Journal of Medical Ethics, Mumbai

Dr Amar Jesani, Editor, Indian Journal of Medical Ethics, Mumbai

Adv Veena Johari, Advocate, Courtyard Attorneys, Mumbai

**Adv Anand Grover,** Senior Advocate, Former UN Special Rapporteur on the Right to Health (2008-14), Director, Lawyers Collective, Mumbai/Delhi

Dr Babu KV, Public Health Activist, Kannur

**Ms Brinelle Dsouza**, Co-convenor, Jan Swasthya Abhiyan, Mumbai, and faculty member, School of Social Work, Tata Institute of Social Sciences, Mumbai

**Dr Chayanika Shah**, Independent Researcher and Retired College Teacher, Mumbai

Dr George Thomas, Orthopaedic Surgeon, Chennai

**Dr Imrana Qadeer**, Former Professor, Centre of Social Medicine and Community Health, JNU, New Delhi

Dr KR Antony, Paediatrician and Public Health Consultant, Kochi

Ms Laxmi Murthy, Journalist, Bengaluru

Ms Malini Aisola, Public Health Professional, New Delhi

Dr Mira Shiva, Public Health Physician, Delhi

**Dr Mohan Rao**, Independent Public Health Researcher, Bengaluru, and former Professor, Centre of Social Medicine and Community Health, JNU, New Delhi **Dr Prabir Chatterjee**, Independent Public Health Consultant, Kolkata

Dr Ramani Akturi, Public Health Physician, Bhopal

Dr Ravi Dsouza, Community Health Physician, Bhopal

Dr Sanjay A Pai, Pathologist, Bangalore

**Dr Sanjay Nagral**, Director, Department of Surgical Gastroenterology, Jaslok Hospital and Research Centre, and Head, Department of Surgery, K B Bhabha General Hospital, Mumbai

Ms Sarojini N, Public Health Researcher, New Delhi

Dr Sejal Tambat, Family Medicine Practitioner, Mumbai

Mr S Srinivasan, LOCOST, Vadodara

Dr SP Kalantri, Physician, Sewagram

Dr Siddhartha Das, Theoretical Physicist, Purnea, Bihar

**Sunita Bandewar**, PhD, Independent Researcher in Health and Bioethics, Pune

Dr Sylvia Karpagam, Public Health Doctor and Researcher, Bengaluru

**Dr T Jacob John**, Retired Professor and Head, Department of Clinical Virology, Christian Medical College, Vellore

Dr Vandana Prasad, Public Health Professional, Delhi

Dr Yogesh Jain, Public Health Physician, Chhattisgarh

# References

- Global manual on surveillance of adverse events following immunization. Geneva: World Health Organization; 2014 (Revised March 2016). Available from: https://www.who.int/vaccine\_safety/publications/Global\_Ma nual\_revised\_12102015.pdf?ua= 1
- Covid-19 vaccines: safety surveillance manual. Geneva: World Health Organization; 2020. Available from: https://www.who.int/publications/i/item/10665338400

# Cc:

1. **Mr Rajesh Bhushan**, Secretary, MOHFW, Co-Chair National Expert Group on Vaccine Administration for COVID-19: email: <a href="mailto:secyhfw@nic.in">secyhfw@nic.in</a>

2. Dr S Eswara Reddy, Joint Drugs Controller: email: <u>se.reddy@nic.in</u>

3. Dr P B N Prasad, Joint Drugs Controller: email: pbn.prasad@cdsco.nic.in

4. **Dr Balram Bhargava**, Director General ICMR, & Vice Chair NTAGI: email: secy- <u>dg@icmr.gov.in</u>

5. **Dr Pradeep Haldar**, Deputy Commissioner (Immunisation): email: pradeephaldar@yahoo.co.in

6. **Dr M K Aggarwal**, Deputy Commissioner (UIP): email: <u>drmkagarwal2@gmail.com</u>

7. Mr A K Pradhan, DDC(I), CDSCO: email: <u>akpradhan@cdsco.nic.in</u>

8. **Dr Roderico Ofrin**, Regional Emergencies Director, Office of the WHO Representative India: email: <u>wrindia@who.int</u>

9. **Dr J N Shrivastava**, Executive Director, NHSRC, Chairman National Quality Assurance Committee for AEFI Surveillance Program; email: nhsrcindia@gmail.com

10. **Mr P K Mishra**, Principal Secretary, PMO: email: pkmishra.pmo@gov.in

# Annexure P-2

Date: 1.10.21

Τo,

Shri Narendra Modi, The Hon'ble Prime Minister of India, New Delhi

Shri Mansukh Mandaviya, The Hon'ble Union Minister, Ministry of Health and Family Welfare, New Delhi Email: <u>hfm@gov.in</u>

Dear Sir,

# Subject: Urgent request to investigate the Serious Adverse

## **Event Following Immunization of our Daughter, Karunya (age**

# <u>20 years).</u>

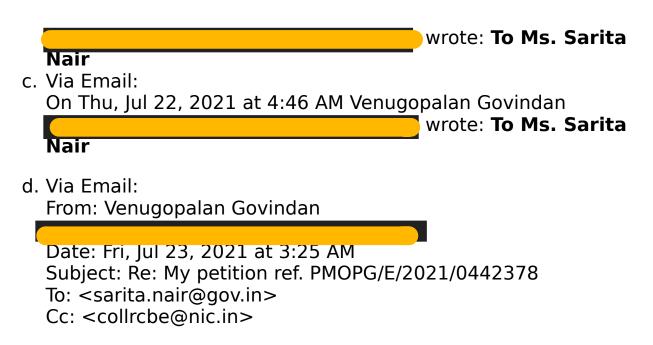
I write to you with a heavy heart to inform you of the untimely, tragic

and avoidable demise of my 20-year old daughter, Karunya

Venugopalan, following Covid-19 vaccination. We have communicated

the same to you as per the following details:

- a. Via Portal: Details for registration number : PMOPG/E/2021/0442378 Name Of Complainant Venugopalan Govindan Date of Receipt 16/07/2021
   Officer Concerns To Officer Name Ms. Sarita Nair Officer Designation Deputy Secretary
- b. Via Email: On Fri, Jul 16, 2021 at 7:45 AM Venugopalan Govindan



However, there was no response from your office or the collectors office.

I would like to once again brief you on the matter of our case. Karunya, our daughter, had received the first dose of the Covishield Covid-19 vaccine on 8.6.2021, and lost her life a few weeks later on 10.7.2021. She was a healthy and bright young woman with no known illnesses or physical disorders. Yet she started experiencing severe AEFI (Adverse Effects Following Immunization) after she received the vaccine shot. She suffered tachycardia, myalgia (due to blood clots), persistent fever, severe inflammation and in spite of treatment in one of the best hospitals (attached to a medical college) in Coimbatore for 3 weeks, she breathed her last on 10<sup>th</sup> July 2021

Having suffered the loss of our young daughter, we would like to urge you to direct the appropriate authorities to actively follow up to record and investigate instances of deaths/serious adverse events following immunization, to advertise extensively in newspaper, television, radio (during prime time) and on social media that any person dying or suffering serious adverse events of vaccination may complain directly to officials and to further direct the authorities to mandatorily record all the cases being reported, and to frame extensive programme for the payment of substantial compensation for those dying or experiencing serious adverse events due to vaccination. We are hearing tragic stories of young housemaids and vegetable vendors dying after vaccination. They were the breadwinners for their families and whole families are shattered after their demise. While we are not particular about compensation for us, such families must be compensated.

Date	Particulars
08/06/2021	Our daughter, Karunya, was administered the
	Covishield vaccine and after vaccination she was

	and a sign of the standard set in the standard for the standard set in the standard se
	experiencing tiredness, had mild fever in the night.
17/06/2021	She started sensing trouble in throat and gargled
	with salt water.
18/06/2021	She woke up with serious symptoms. She could
10,00,2021	
	barely walk, speak or swallow, and was running high
	fever
19/06/2021	An RTPCR test with Microbiological laboratories was
	conducted to test the deceased of COVID. The test
	results came negative.
20/06/2021	Karunya was taken to Aroghya Nursing Home where
	the family normally goes for health issues. The
	Doctor checked and gave her liquid medicines
	saying that her throat is very much inflamed and not
	to give anything solid.
21/06/2021	Since there wasn't much improvement in the
	condition, she was again taken to the hospital where
	the Doctor asked to admit her. To quote the report
	from this hospital "The patient presented with
	complaints of fever since 17.06.2021, along with
	history of throat pain, arthralgia, headache and
	myalgia, and exertional dyspnoea". After admitting

	the Doctor again took a COVID RT PCR test. That
	.also came negative
24/06/21	We, via call, reported the adverse effects to the
	Serum Institute of India
25/06/2021	As the treatment Aroghya Nursing Home didn't yield
	much result (the severe difficulty in walking due to
	pain and the incessant fever) she was shifted to PSG
	Hospitals, a speciality hospital with attached Medical
	college. Dr Murali A, Professor at PSG Medical
	college and Infectious diseases specialist was the
	treating physician.
	There were a variety of investigations including CT
	Scans, Echo, PET scans etc. conducted apart from
	almost daily blood tests. The blood tests
	continuously gave heightened immunomarkers and
	WBC. She was put on a 7 day antibiotics course.
04/07/2021	Finally she was administered anticoagulants and
	steriods which gave her good relief in walking and
	she could walk normally. However the fever didn't
	go away and it was more pronounced in the night.
	The diagnosis was firmed up as Multisystem

	Inflammatory Syndrome
06/07/2021	At night our daughter had fever with severe chills
	and shaking of whole body.
07/07/2021	Doctor advised starting IV IgG on 7th morning and it
	was started. Unfortunately there was a sudden drop
	in her health on that afternoon, and her BP, pulse,
	O2 level all started dropping alarmingly. She was put
	on O2, and was rushed to the ICU. From there it was
	downhill and she never recovered.
10/07/2021	Our daughter breathed her last.
22/07/2021	In response to the series of emails written by us,
	Doctor Sumit Tandon, Senior Manager, Clinical Re-
	search and Pharmacovigilance Dept., Serum Insti-
	tute of India Pvt. Ltd., 212/2, Hadapsar, Pune - 411
	028, < <u>sumit.tandon@seruminstitute.com</u> >, wrote: Dear Mr Venu-
	gopalan, Thanks for sharing all the reports. Cur-
	rently, Covid-19 infection is considered as the cause
	of Multisystem Inflammatory Syndrome. Kindly refer
	the details regarding Multisystem Inflammatory Syn-
	drome from Centers for Disease Control and Preven-
	tion, USA at https://www.cdc.gov/mis/. Covishield does not

contain SARS-CoV-2 virus and cannot cause Covid-19 infection. Also, Covishield is not known to cause multisystem inflammatory syndrome. However, we will continue to collect data for risk benefit analysis of the vaccine for vaccine safety.

After the passing of our daughter, we were compelled to do our own research regarding the Covid-19 vaccines and especially Covishield (Astrazeneca) vaccine. It was shocking to find out that Covishield vaccine is banned or age-restricted in 14 countries. There is a clear link between blood clots and Covishield vaccine, especially experienced by young people. We are deeply pained that this information was not available to us before we decided to take the vaccine.

Please find below some references of our research:

1. <u>https://www.cityam.com/why-have-almost-half-eu-countries-</u> restricted-use-of-the-astrazeneca-vaccine/

2. <u>https://www.wionews.com/world/spain-puts-maximum-age-limit-for-</u> receiving-astrazeneca-vaccine-361744 3. <u>https://7news.com.au/lifestyle/health-wellbeing/astrazeneca-likely-</u> <u>to-be-phased-out-as-australias-covid-vaccine-forecast-is-revealed-c-</u> <u>3205325</u>

# 4. https://www.bbc.com/news/world-australia-57549796

We are also very disappointed with the AEFI reporting & monitoring mechanisms. All the authorities were reluctant to call the experience of our daughter an adverse event due to the vaccine. The state authorities responsible for the AEFI investigation have refused to give us any details of the case.

We are deeply saddened to see various states, public and private institutions and companies mandating these experimental vaccines. When these vaccines have a potential risk of death, it must be left to the individual to decide whether they wish to take the risk or not.

In view of the above mentioned facts and circumstances, we seek the following relief from your Office:

# Accurate information on Vaccines to be provided to the people for informed consent and decision making

1. We request the authorities administering the Covid vaccine drive to provide the following:

a. Fact sheets or vaccine inserts to be provided to each vaccine recipient at the time of registration (through Cowin, whatsapp or walk-in). The fact sheet to include the list of ingredients, possible allergic reactions, risk of mild, moderate and severe life threatening side effects like blood clots leading to death. This information needs to be also PROMINENTLY displayed at all vaccination sites.

b. Blood clots occurring in the brain, heart, etc. in certain people, especially young girls/women, should be listed as an Adverse
Event for Covid Vaccines as part of the informed consent.
c. All advertisements, ringtones, TV commercials should stop
making misleading claims of safety such as 'vaccines
manufactured in India are **completely safe'**. The
advertisements should include without fail information on
possible adverse effects in some like blood clotting, which could
be fatal.

2. Each citizen receiving the vaccination be given guidance as to the early signs of adverse reactions and recommended certain precautionary tests leading to early detection. If caught early, appropriate timely tests and treatment can save lives. 3. Those not eligible for the covid vaccination due to allergies and/or certain health conditions be assessed for the same and informed as such.

4. Protocols to identify and treat blood clots post vaccination, to be provided to the medical fraternity.

#### Usable and transparent AEFI registration & data

5. That the Government is requested to enable the following:

a. To be able to register adverse events after vaccination through COWIN portal and once an adverse event is registered by a vaccine recipient (or relatives in case of deaths or v. serious adverse event), he/she should be able to track the status of his/her report through the portal. The AEFIs registered should be examined and rulings passed on them on a timebound manner such as 2-3 weeks for any deaths reported, and 4-6 weeks for adverse events requiring hospitalisation etc.

b. To be able to register adverse events after vaccination through Toll Free Number - 1075 and once an adverse event is registered by a vaccine recipient (or relatives in case of deaths or v. serious adverse event), he/she should be able to track the status of his/her report through the same number. c. To be able to register adverse events after vaccination through Whatsapp Number - 9013151515 and once an adverse event is registered by a vaccine recipient (or relatives in case of deaths or v. serious adverse event), he/she should be able to track the status of his/her report through the same whatsapp chat.

d. The Adverse events data (without identifying victims) should be transparently accessible in COWIN portal and in

www.cowin.gov.in for public use.

e. The entire process of AEFI be kept transparent to the victim's family, and provide a status of the case when requested by the family. As currently the victim's family has no way of knowing the status of an AEFI case and are kept completely uninformed.

#### **Reports qua Discontinuation/Restriction of Covishield**

6. That the Government is requested to phase out or at least age limit the use of COVISHIELD in younger population. COVISHIELD (known as astrazeneca vaccine globally) is

a. Not approved for use in many countries (USA, Switzerland, Denmark...)

b. Age-limited for use in many countries (Italy, Germany, France ..)

#### c. Being phased out in Australia

This is to be done at the earliest to prevent any loss of lives or serious adverse effects that are happening with massive vaccination drives.

#### Voluntary administration of the Vaccine

7. For an order directing all authorities and private parties to follow the Union of India's decision to make the administration of vaccine purely voluntary. There should be no denial of services like entry to education institutions, public places etc based on non-vaccinated status of an individual.

#### Disclosure

8. For an order directing the respondents to publicly disclose the following information as sought for by 24 eminent health rights experts by letters dated 31.01.2021 (at Annexure 1) and 16.03.2021 (at Annexure 2) asunder:

a. Full details of the committees that conducted the investigation and causal assessment including the procedure followed, the findings and the basis on which conclusions were arrived at as to whether the deaths were related to the vaccine or not.

b. Complete information on all deaths, severe and serious AEFI's in the vaccine rollout.

c. Full details of the affiliations and the qualifications of all AEFI investigation committee members including any group of experts overseeing the vaccine rollout.

d. The minutes of all the investigation committee meetings.

## Compensation

9. That the authorities be directed to frame and publish an extensive programme for the payment of substantial compensation for those dying or experiencing serious adverse events of vaccination where the deaths and serious adverse events are very likely/certainly, probably, possibly a result of the vaccine in accordance with the Brighton Criteria as accepted in the "Adverse Events Following Immunization (AEFI): Causality Assessment" published by WHO in 2005. This must be definitely done for those victims who were the bread winners of their family.

We look forward to a positive response from you. We hope to see your office take positive measures to address our aforementioned prayers.

With Warm Regards,

Sujini Venugopalan & Venugopalan Govindan

#### Annexure 1

#### **URGENT ATTENTION**

Date: 31 January 2021

#### 1. Hon'ble Dr. Harsh Vardhan

Union Minister Ministry of Health and Family Welfare, New Delhi Email: hfm@gov.in

#### 2. Dr. V. G. Somani

Drugs Controller General of India New Delhi Email: dci@nic.in

#### 3. Dr. V. K. Paul

Member, NITI Aayog Chair, National Expert Group on Vaccine Administration For COVID-19 Email: vinodk.paul@gov.in; vinodkpaul@gmail.com  Dr. Renu Swarup Secretary, Department of Biotechnology Chair, NTAGI Email: secy@dbt.nic.in

# Subject: Investigations of deaths of 11 healthcare and frontline workers following administration of COVID-19 vaccine

Dear Sir(s) and Madam,

We write to you with the trust that you will take cognizance of our concerns and respond promptly. We refer to the deaths of eleven health and frontline workers between 16 and 30 January, 2021, following administration of the COVID-19 vaccine, as reported in the media. The deaths took place in the States of Uttar Pradesh, Karnataka, Andhra Pradesh, Rajasthan, Telangana, Gurugram, Odisha, and Kerala.

The 11 deaths, reported in the media, took place between a few hours and five days of persons (primarily 42 to 56 years old) healthcare workers, and a frontline worker (23 years old), taking the vaccines, and all have been ascribed to cardiovascular problems or "brain stroke". The vaccine taken in each case was Covishield.

Though the district/state officials have stated that none of the deaths are related to the vaccine, the reports of the District, State and National AEFI Committees on the assessment of these deaths and other serious AEFIs have not been released. No details of who investigated the deaths, and the methodology used for each investigation, have been made public. The National Committee has an obligation to investigate possible patterns in causative factors for these deaths.

We would like to bring to your notice that the 11 deaths meet the WHO's definition of a "**cluster" of serious AEFIs** as given in its *Covid-19 vaccines: safety surveillance manual* -- "when two or more AEFIs related in time, place or by vaccine occur" (1). Guidelines for investigation of cluster AEFIs are given in the WHO's global manual for surveillance of adverse events following immunization (2). AEFIs must be investigated urgently in order to issue warnings to people who should not take it due to contraindications, to correct errors, to reassure the public, as well as to identify potential serious problems in the vaccine. The algorithm for cluster AEFI investigation can rule out errors in manufacturing or administration, anxiety clusters, and coincidental events, *to identify signals for further investigation*.

The health and frontline workers who died had volunteered to take the vaccine with the trust in your decision to give emergency approval to the vaccine to protect them from a

serious disease. They are owed some respect and dignity, and they have a right to at least a prompt, thorough and transparent investigation of their deaths, and action based on that investigation.

We strongly urge you to provide the following information and place it in the public domain:-

- 1. *Has an investigation into the 11 deaths taken place?* Please give details of the committees that conducted the investigation and causal assessment. What procedure did the investigations follow, what were the findings, and on what basis was it concluded that the deaths were not related to the vaccine?
- 2. *Have there been any other reports of deaths or other severe or serious AEFIs following administering of the covid19 vaccine?* Please place complete information on **all deaths, severe and serious AEFIs** in the COVID-19 vaccine rollout, and their investigation, in the public domain. This information should include the numbers, date of vaccination, details of the AEFI, place, investigation status and results. Please also release the minutes of the National, State and District AEFI Committees.
- 3. Why are the names, affiliations and qualifications of all AEFI investigation committee members at the District, State and Central level not in the public domain? Please make the names and affiliations of Committee Members public.
- 4. *Is there any group of experts overseeing the vaccine rollout?* Please make their names, expertise and affiliations public.
- 5. Has any committee of experts discussed whether the vaccine rollout should be paused pending final investigation and determination in the deaths and other serious AEFIs reported? Please release the minutes of the committee meetings where such discussions took place, with the explanation for not temporarily pausing vaccination.
- 6. *Will the programme be amended based on deaths, serious AEFIs investigation findings?* Will the programme be re-assessed and amended, with warnings, informed consent, etc., prior to the completion of the rollout of the first dose and prior to the commencement of the rollout of the second dose of the vaccine?
- 7. *Will any no-fault compensation be paid to the families of the healthcare and frontline workers who died?* This is all the more important because the COVID-19 vaccines are not *fully approved* but only given emergency use approval with limited data.

We request you to kindly acknowledge this letter and to respond promptly to our queries and concerns. We hope you will take steps in the right direction so as to ensure that trust, transparency, and honesty is inculcated and maintained in the vaccine rollout programme.

#### Regards,

Ms Sandhya Srinivasan, Consulting Editor, Indian Journal of Medical Ethics, Mumbai Dr Amar Jesani, Editor, Indian Journal of Medical Ethics, Mumbai Adv Veena Johari, Advocate, Courtyard Attorneys, Mumbai Dr Antony R Kollanur, Consultant Public Health, Kochi Dr Babu KV, Public Health Activist, Kerala Dr Chayanika Shah, PhD, Queer Feminist Activist and Science Studies Researcher, Mumbai Mr Chinu Srinivasan, Low Cost Standard Therapeutics (LOCOST), Vadodara Dr George Thomas, Orthopaedic Surgeon, Chennai Dr Imrana Qadeer, Former Professor, Centre of Social Medicine and Community Health, JNU, New Delhi Ms Laxmi Murthy, Journalist, Bangalore Ms Malini Aisola, Public Health Researcher, Delhi Dr Mira Shiva, Co-convenor, All India Drug Action Network, Delhi Dr Mohan Rao, Former Professor, Centre of Social Medicine and Community Health, JNU, New Delhi Dr Prabir Chatterjee, Independent Public Health Consultant, Bankura Dr Ramani Akturi, Independent Public Health Physician, Bhopal Dr Ravi Dsouza, Community Health Physician, Bhopal Dr Sanjay A Pai, Working Editor, Indian Journal of Medical Ethics, Bangalore Dr Sanjay Nagral, Director, Department of Surgical Gastroenterology, Jaslok Hospital and Research Centre, Mumbai Dr Sejal Tambat, Family Medicine Practitioner, Mumbai **Dr SP Kalantri**, Physician, Sewagram Dr Sylvia Karpagam, Public Health Doctor and Researcher, Bangalore **Dr T Jacob John**, Retired Professor and Head, Department of Clinical Virology, Christian Medical College, Vellore Dr Vandana Prasad, Public Health Professional, Delhi

### Cc:

1. **Mr. Rajesh Bhushan**, Secretary, MOHFW, Co-Chair National Expert Group on Vaccine Administration for COVID-19: email: secyhfw@nic.in

2. Dr. S Eswara Reddy, Joint Drugs Controller: email: se.reddy@nic.in

3. Dr. PBN Prasad, Joint Drugs Controller: email: pbn.prasad@cdsco.nic.in

4. **Dr. Balram Bhargava**, Director General ICMR, & Vice Chair NTAGI: email: secy-dg@icmr.gov.in

5. **Dr. Pradeep Haldar**, Deputy Commissioner (Imm.I/C): email: pradeephaldar@yahoo.co.in

6. **Dr. M K Aggarwal**, Deputy Commissioner (UIP): email: drmkagarwal2@gmail.com 7. **Mr. A K Pradhan**, DDC(I), CDSCO: email: akpradhan@cdsco.nic.in

8. **Dr. Roderico Ofrin**, Regional Emergencies Director, Office of the WHO Representative India: email: wrindia@who.int

9. **Dr. J N Shrivastava**, Executive Director, NHSRC, Chairman National Quality Assurance Committee for AEFI Surveillance Program; email: nhsrcindia@gmail.com 10. **Mr. P K Mishra**, Principal Secretary, PMO: email: pkmishra.pmo@gov.in

#### References

- Covid-19 vaccines: safety surveillance manual. Geneva: World Health Organization; 2020. P. 63. Available from: https://www.who.int/publications/i/item/10665338400
- Global manual on surveillance of adverse events following immunization. Geneva: World Health Organization; 2014 (Revised March 2016). P. 58. Available from: https://www.who.int/vaccine\_safety/publications/Global\_Manual\_revised\_12102 015.pdf?ua=1

### Annexure 2

# Date: 16 March 2021

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 Hon'ble Dr Harsh Vardhan Union Minister Ministry of Health and Family Welfare New Delhi Email: <u>hfm@gov.in</u>

2. Dr VG Somani Drugs Controller General of India New Delhi Email: <u>dci@nic.in</u>

3. Dr VK Paul Member, NITI Aayog Chair, National Expert Group on Vaccine Administration For COVID-19 Email: vinodk.paul@gov.in; <u>vinodkpaul@gmail.com</u>

4. Dr Renu Swarup Secretary, Department of Biotechnology Chair, NTAGI Email: <u>secy@dbt.nic.in</u> 5. Dr NK Arora Member, National Task Force on COVID-19 Advisor, National AEFI Committee, Delhi Email: nkarora@inclentrust.org; narendrakumararora@gmail.com

Urgent investigation of deaths and serious adverse events following administration of COVID-19 vaccine

We are writing to you as people working in public health, ethics, medicine, law, and journalism, and as members of the public, who support the immunisation programme. We wrote to you earlier on 31 January 2021 expressing our concerns regarding the lack of information on the investigations of deaths following COVID-19 vaccination in India. We are disappointed at the government's silence on our letter while further reports of deaths following administration of COVID-19 vaccine are appearing in the media.

The government is responsible for ensuring safety of all vaccines and particularly those administered through a government programme. This includes monitoring and surveillance of adverse events following immunisation (AEFIs). AEFIs are to be investigated through well-defined procedures for vaccine pharmacovigilance and the reports made available in the public domain, for trust-building and transparency. This is especially important for new vaccines such as the COVID-19 vaccines currently being rolled out across the country under emergency use authorisation, targeted to millions of people.

We understand that at least 65 deaths have occurred following vaccination for COVID-19 since the vaccination campaign started on January 16. However, the National AEFI Committee's investigation findings of only two of these deaths have been made public.

Till now, no case of serious AEFI including death has been attributed to the vaccine. Denmark, Iceland, Norway, Italy, France, Bulgaria, Germany, Luxembourg, Estonia, Lithuania, Latvia and Ireland have paused immunisation with the Astra Zeneca vaccine pending investigation of a small number of post-vaccination deaths from intravascular clotting/ thromboembolic events, while Austria has suspended the use of certain batches. Media reports indicate that many deaths post vaccination with COV-ISHIELD, AstraZeneca's vaccine which is being manufactured in India by the Serum Institute of India, occurred due to cardiac arrest, cerebral venous thrombosis and stroke.

We believe that due to the possible linkages of vaccination and blood clotting, all these deaths and adverse events should be reviewed together for a possible causal relationship with the vaccine. We raise one possibility: human cells bearing SARS-CoV-2 spikes displayed on the surface, are, for the ACE 2 receptors, like the virus itself. The event cascade leading to clotting is a part of the pathogenesis of the virus-human interactions. We suggest that there is a possibility of this being enacted by some vaccines.

Reports of other serious AEFIs including neurological symptoms, hemiplegia and Guillain-Barre syndrome also need to be investigated. As the vaccination drive has been expanded to include persons over 60 years and persons above 45 years with specified morbidities, it is all the more important to investigate any possibilities of the COVID-19 vaccines triggering serious AEFI in people with certain medical conditions, who are the very people in need of vaccination. Could they be 'predisposed' to aggravation of their basic condition?

We note with concern that critical updates to the fact sheets recommended by the CDSCO's Subject Expert Committee have not been issued, even though they are meant to provide additional guidance and clarify use of the vaccines in persons such as those with allergies, who are immunocompromised or using

immunosuppressants, or using blood thinners/anti-coagulants.

There are gaps in AEFI investigations at the local level, affecting the quality of evidence submitted to State and National AEFI Committees who depend on these findings for making causality assessments. The National AEFI Committee also has a critical role in assessing cases that present as a cluster and to explore potential common pathways.

In our letter dated January 31, 2021, we asked for details of all investigations into deaths and other serious AEFIs, as well as the minutes of AEFI monitoring committees, and details of all AEFI committee members and other experts overseeing the vaccine rollout. We have not received any response. We also note that the government has stopped sharing any details of AEFIs after February 26, 2021.

Lakhs of people in India are being administered the COVID-19 vaccines every day in the confidence that the vaccine will protect them against severe disease and death. The vaccine programme owes them complete information on the vaccines, a vaccination protocol that minimises the risk of harm, and an assurance of thorough and transparent investigation of injuries and death following immunisation. They are also owed medical care, and compensation for harm suffered post vaccination. The government has not met these obligations.

The government must immediately undertake complete, time-bound and transparent investigation of all deaths and other serious adverse events following vaccination with the COVID-19 vaccine.

The following must be put in the public domain: 1. For each of the vaccines rolled out, details of all serious AEFIs as of March 16, 2021, and the status of investigation;

2. Findings of all completed serious AEFI investigations, including:

a. cause of death by clinical diagnosis;

b. autopsy findings when possible, or verbal autopsy, to confirm or revise the clinical diagnosis;

c. causality assessment and the reasoning behind that assessment;

d. aetiology; if no aetiology is found, the death must provisionally be attributed to the vaccine, and

e. the process undertaken by the various AEFI committees, including whether the WHO guidelines for investigation of AEFI occurring as cluster have been strictly followed,

f. cause of other AEFIs, and the causality assessments by the various committees.

Based on the findings of investigations the vaccination protocols should be modified with screening procedures that decrease the prob-

ability of serious adverse events following immunisation, if found necessary.

Awaiting a response,

Thanking you,

Sincerely,

Ms Sandhya Srinivasan, Consulting Editor, Indian Journal of Medical Ethics, Mumbai

Dr Amar Jesani, Editor, Indian Journal of Medical Ethics, Mumbai

Adv Veena Johari, Advocate, Courtyard Attorneys, Mumbai

Adv Anand Grover, Senior Advocate, Former UN Special Rapporteur on the Right to Health (2008-14), Director, Lawyers Collective, Mumbai/Delhi

Dr Babu KV, Public Health Activist, Kannur

**Ms Brinelle Dsouza**, Co-convenor, Jan Swasthya Abhiyan, Mumbai, and faculty member, School of Social Work, Tata Institute of Social Sciences, Mumbai

**Dr Chayanika Shah**, Independent Researcher and Retired College Teacher, Mumbai

Dr George Thomas, Orthopaedic Surgeon, Chennai

**Dr Imrana Qadeer**, Former Professor, Centre of Social Medicine and Community Health, JNU, New Delhi

Dr KR Antony, Paediatrician and Public Health Consultant, Kochi

Ms Laxmi Murthy, Journalist, Bengaluru

Ms Malini Aisola, Public Health Professional, New Delhi

Dr Mira Shiva, Public Health Physician, Delhi

**Dr Mohan Rao**, Independent Public Health Researcher, Bengaluru, and former Professor, Centre of Social Medicine and Community Health, JNU, New Delhi **Dr Prabir Chatterjee**, Independent Public Health Consultant, Kolkata

Dr Ramani Akturi, Public Health Physician, Bhopal

Dr Ravi Dsouza, Community Health Physician, Bhopal

Dr Sanjay A Pai, Pathologist, Bangalore

**Dr Sanjay Nagral**, Director, Department of Surgical Gastroenterology, Jaslok Hospital and Research Centre, and Head, Department of Surgery, K B Bhabha General Hospital, Mumbai

Ms Sarojini N, Public Health Researcher, New Delhi

Dr Sejal Tambat, Family Medicine Practitioner, Mumbai

Mr S Srinivasan, LOCOST, Vadodara

Dr SP Kalantri, Physician, Sewagram

Dr Siddhartha Das, Theoretical Physicist, Purnea, Bihar

**Sunita Bandewar**, PhD, Independent Researcher in Health and Bioethics, Pune

Dr Sylvia Karpagam, Public Health Doctor and Researcher, Bengaluru

**Dr T Jacob John**, Retired Professor and Head, Department of Clinical Virology, Christian Medical College, Vellore

Dr Vandana Prasad, Public Health Professional, Delhi

Dr Yogesh Jain, Public Health Physician, Chhattisgarh

References

- Global manual on surveillance of adverse events following immunization. Geneva: World Health Organization; 2014 (Revised March 2016). Available from: https://www.who.int/vaccine\_safety/publications/Global\_Ma nual revised 12102015.pdf?ua= 1
- Covid-19 vaccines: safety surveillance manual. Geneva: World Health Organization; 2020. Available from: https://www.who.int/ publications/i/item/10665338400

# Cc:

1. **Mr Rajesh Bhushan**, Secretary, MOHFW, Co-Chair National Expert Group on Vaccine Administration for COVID-19: email: <u>secyhfw@nic.in</u>

2. Dr S Eswara Reddy, Joint Drugs Controller: email: <u>se.reddy@nic.in</u>

3. **Dr P B N Prasad**, Joint Drugs Controller: email: pbn.prasad@cd-sco.nic.in

4. **Dr Balram Bhargava**, Director General ICMR, & Vice Chair NTAGI: email: secy- <u>dg@icmr.gov.in</u>

5. **Dr Pradeep Haldar**, Deputy Commissioner (Immunisation): email: <u>pradeephaldar@yahoo.co.in</u>

6. **Dr M K Aggarwal**, Deputy Commissioner (UIP): email: <u>drmkagarw-al2@gmail.com</u>

7. Mr A K Pradhan, DDC(I), CDSCO: email: <u>akpradhan@cdsco.nic.in</u>

8. **Dr Roderico Ofrin**, Regional Emergencies Director, Office of the WHO Representative India: email: <u>wrindia@who.int</u>

9. **Dr J N Shrivastava**, Executive Director, NHSRC, Chairman National Quality Assurance Committee for AEFI Surveillance Program; email: nhsrcindia@gmail.com

10. **Mr P K Mishra**, Principal Secretary, PMO: email: pkmishra.pmo@gov.in

## IN THE SUPREME COURT OF INDIA CIVIL ORIGINAL JURISDICTION

I.A. No. \_\_\_\_\_ of 2021

In

WRIT PETITION (CIVIL) \_\_\_\_\_ OF 2021

(Under Article 32 of the Constitution of India)

#### IN THE MATTER OF:

Rachana Gangu & Anr.

... Petitioners

Versus

Union of India & Ors.

...Respondents

# APPLICATION FOR EXEMPTION FROM FILING NOTARIZED <u>AFFIDAVIT</u>

To,

HON'BLE CHIEF JUSTICE OF INDIA AND HIS COMPANION JUSTICES OF THE SUPREME COURT OF INDIA

# HUMBLE PETITION OF THE APPLICANT HEREIN

MOST RESPECTULLY SHOWETH:

1. The Petitioners No. 1 & 2 are compelled to file the present Writ Petition due to the untimely, tragic and avoidable demise of their 18 year and 20 year old daughters respectively. Petitioner No. 1's daughter received the first dose of the Covishield Covid-19 vaccine on 29.5.2021 and lost her life a few weeks later on 19.6.2021. Petitioner No. 2's daughter received the first dose of the Covishield Covid-19 vaccine on 8.6.2021 and lost her life a few weeks later on 10.7.2021. The Petitioners' respective

daughters were healthy and bright young women with no known illnesses or physical disorders. Yet they started experiencing severe AEFI (Adverse Effects Following Immunization) soon after they received the vaccine shot. Petitioner No. 1's daughter suffered rapid decrease in her platelet count, incessant headache, vomiting and seizures, and physical, mental and emotional trauma, before she eventually lost her life while on life support, less than three weeks after she received the vaccine shot. Petitioner No. 2's daughter suffered from heightened immunomarkers and WBC, fever, trouble in throat, arthralgia, headache and myalgia, and exertional dyspnoea before she eventually lost her life. It is pertinent to note neither Petitioners nor their daughters were informed in advance of the risk of such severe AEFI and their informed consent was not taken before administering of the vaccine.

- 2. Having suffered the loss of their young daughters, the Petitioners are filing this Writ Petition seeking a writ, order or direction for appointment of an expert medical board, independent of the Government, to forthwith inquire into and investigate into the deaths of the daughters of Petitioners No. 1 & 2 and to share the report of the investigation with the Petitioners, as well as a writ, order or direction to the said expert medical board to prepare a protocol for early detection and timely treatment for the AEFI due to Covid-19 vaccine; and compensation to the Petitioners.
- 3. That due to the spread of the Covid-19 pandemic and travel restrictions imposed in many parts of the country, it is not possible for the Applicant to file a notarized Affidavit. Thus the Applicants seek exemption from filing a notarized Affidavit.

4. This application is made in the interest of justice.

#### PRAYER

- 5. Hence, in view of the facts and circumstances explained above, it is prayed before this Hon'ble Court as under:
  - a. For an order exempting the Applicants from filing a notarized Affidavit; and
  - b. For any other order or direction that this Hon'ble Court may deem fit and appropriate in the interest of justice.

AND FOR THIS ACT OF KINDNESS, THE PETITIONER AS IN DUTY BOUND SHALL EVER BE GRATEFUL.

Filed on:

Place: New Delhi

Satya Mitra (Advocate for Applicant)

# IN THE SUPREME COURT OF INDIA CIVIL ORIGINAL JURISDICTION I.A. No. \_\_\_\_\_ of 2021 In WRIT PETITION (CIVIL) \_\_\_\_\_ OF 2021 (Under Article 32 of the Constitution of India) IN THE MATTER OF: Rachana Gangu & Anr. \_\_\_\_\_Petitioners Versus Union of India & Ors. \_\_\_\_\_\_

#### Affidavit

I, Rachana Gangu, Aged about 44 years, D/o G. Ranjit Narayan, R/c Hyderabad, Telangana- 500089, do hereby solemnly affirm and declare on oath asunder:

- 1. That I am the Petitioner No. 1 in the abovenamed Petition. I am well conversant with the facts and circumstances of the case and hence competent to swear this Affidavit on behalf of both Petitioners No. 1 & 2.
- 2. That I have read the contents of the accompanying Application as shown and explained to me. I have understood the contents thereof.

- 3. That the Annexures annexed with this Writ Petition are true copies of their respective originals.
- 4. This Writ Petition is being filed under my instructions and the contents thereof are true to the best of my knowledge and belief and nothing material has been concealed



#### **VERIFICA TION:**

Verified at New Delhi on this day the <u>27th</u> of <u>October</u>, 2021 that the contents of the above affidavit are true and correct to the best of my knowledge, that no part of it is false and nothing material has been concealed therefrom.



DEPONENT

#### IN THE SUPREME COURT OF INDIA

Special Leave Petition (Crl/Civil) No. \_\_\_\_\_ of 2021

Civil/Crimimal Appeal/Transfer/Writ Petition No. \_\_\_\_\_ of 2021

#### IN THE MATTER OF:

Rachana Gangu & Anr.

... Petitioner

Versus

Union of India & Ors.

... Respondent

#### INDEX OF FILING

S.No.	Particulars	Copies	Court Fees
1.	Listing Proforma		
2.	Synopsis and List of		
	Dates		
3.	Writ Petition with		
	Affidavit		
4.	Annexure P-1 to P-2		
5.	I.A for seeking		
	exemption from filling		
	notarized affidavit		
6.	Vakalatnama		

Filed on: 27.10.2021

Code No. 1852

I.C. No. 4853

Satya Mitra Advocate for the Petitioner 576, Masjid Road, Jangpura New Delhi-110014

#### IN THE SUPREME COURT OF INDIA

CIVIL/CRIMINAL/ORIGINAL/APPELLATE/JURISDICTION S.L.P.(C/Crl.)/Civil/Crl. Appeal/Writ Petition/T.P.No.\_\_\_\_2

\_20 21

Rachana Gangu & Anr.

Appellant(s) Petitioner(s)

Respondent(s)

#### VERSUS

Union of India & Ors.

#### VAKALATNAMA

#### I/We Rachana Gangu & Anr.

Appellants(s)/Petitioner(s)/Respondent(s) /Opposite party in the above Suit/ Appeal: Petition/ Reference do hereby appoint and retain <u>Satya Mitra</u> Advocate of the Supreme Court to act and appear for me/us in the above Suit/ Appeal/ Petition/ Reference and or my /our behalf to conduct and prosecute (or defend) the same and all proceedings that may be taken in respect of my application connected with the same of any decree order passed therein, including proceedings in taxation and application for Review, to file and obtain return of documents, and to deposit and receive money on my/ or behalf in the said Suit Appeal/ Petition Reference and in application of Review, and to represent me/us and to take all necessary steps on my /our behalf in the above matter, I/We agree to ratify all acts done by the aforesaid Advocate in pursuance of this authority.

Dated this the 27th day ofOc	<u>ctober</u> 20 2	, <b>I</b>
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Accepted

Mr. Satya Mitra



Petitioner No. 1 (Rachana Gangu)

Petitioner No.2 (Venugopalan Govindan)

Govindan ) APPELLANT(s)/PETITIONER(s)/ CAVEATOR(s)/RESPONDENT(s)

#### ADVOCATE SUPREME COURT

#### **MEMO OF APPEARANCE**

To,

The Registrar, Supreme Court of India New Delhi

Sir.

Please enter my appearance on behalf on the Petitioner(s) /Appellant(s)/ Respondent(s) /Intervenor in the matter above mentioned.

Dated this the 27th day of October 20 21

Yours faithfully,

Advocate for Petitioner(s)/Appellant(s)/Respondent(s)