

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
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3. Dr. V. K. Paul

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For COVID-19
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4. Dr. Renu Swarup

Secretary, Department of Biotechnology
Chair, NTAGI
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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,

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Cc:

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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

1. *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_12102015.pdf?ua=1