Date: 16 March 2021

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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,

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2. *Covid-19 vaccines: safety surveillance manual.* Geneva: World Health Organization; 2020. Available from: https://www.who.int/publications/i/item/10665338400

Cc:

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