ALL INDIA PEOPLE's SCIENCE NETWORK (AIPSN)

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Sub: EUA of anti-Covid vaccines in India

Please find attached the statement from AIPSN on the need for **"On Scientific, Independent and Transparent Process for Emergency Use Authorization (EUA) of anti-Covid Vaccines in India"**

Yours sincerely

Sd/-
P.Rajamanickam
General Secretary, AIPSN

<u>All India Peoples Science Network (AIPSN) Statement</u>
On Scientific, Independent and Transparent Process for
Emergency Use Authorization (EUA) of anti-Covid Vaccines in India

AIPSN expresses satisfaction that the Subject Expert Committee (SEC) of the Central Drugs Standards Control Organization (DSCCO), at its meeting on 9th December 2020, has kept pending any recommendations on applications for Emergency Use Authorization (EUA) of Covid-19 Vaccines by Serum Institute of India (SII) manufacturing the Oxford Astra Zeneca vaccine of the UK, and by Bharat Biotech making the indigenously developed ICMR/NIV vaccine. The SEC sought additional data from SII relating to its Phase-III trials in India and the pending regulatory approval process in the UK. In the case of Bharat Biotech, the SEC said it would proceed only after reviewing data from its on-going Phase-3 trials in India, whereas it had submitted only Phase-I/II data. The regulatory agency Drugs Controller General of India (DGCI) was to have decided on grant of EUA based on the recommendations of the SEC. The SEC, at least for now, has rightly asserted its role regarding scientific assessment of vaccine candidates independent of political, bureaucratic or commercial interests.

The SEC decision has come against the context of several recent public statements by the Health Secretary, Dr.V.K.Paul of Niti Aayog heading the National Task Force, and by DG ICMR pushing for a quick grant of EUA for these and other applicants, rather than respecting due process and sientific evaluation of data relating to safety and efficacy. DG ICMR in particular sought to undermine the importance of Phase-III trials data and suggested that some vague "cost-benefit assessment" would instead suffice for granting EUA, ignoring the obvious conflict of interest since one of the candidates has indeed been developed by an IMR laboratory!

The urgency for approval and deployment of vaccines is no doubt of importance, but not at the cost of safety or potential impact in reducing infection, transmission and severe illness or mortality. Robust data enabling a more scientific and considered decision based on Phase-3 trials data, whether from India or abroad, is likely to become available in a few weeks in any case. With the national case load on a declining trend, there is opportunity to hasten slowly as WHO recommends. Self-reliance and encouraging indigenous research and manufacturing industry are undoubtedly important, but sloppy or unscientific decision-making relating to public health will only damage the reputation of Indian science and regulatory processes, far outweighing any brownie points gained by rolling-out of a vaccination programme a few weeks early, but which may later turn out to be problematic. Rolling out a vaccine without a proper appraisal of safety and efficacy may also lead to a backlash, adding to existing vaccine skepticism or hesitancy.

AIPSN therefore calls upon the SEC and DCGI to fearlessly conduct a thorough scientific assessment of available early data from Phase-3 trials in India or abroad independent of political, bureaucratic and commercial interests in deciding upon EUA for different vaccine candidates. AIPSN further calls for releasing the data based on which any recommendation is made in the interests of transparency, gain confidence of the scientific and medical community in India and internationally, and so as to allay any fears about safety and efficacy of vaccines to be rolled out. This is especially crucial if India is to contribute to the global fight against the Covid-19 pandemic through its indigenously developed vaccines. While granting EUA, it is also important to set up extensive surveillance of the vaccination programme, and to continue with rigorous Phase-III trials and peer review and publication of its data.

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