

ALL INDIA PEOPLE's SCIENCE NETWORK (AIPSN)

Regd. No. PKD/CA/62/2020.



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05.7.2020

To
The Editor
Press/Media

Please find attached below the press release of the statement on **AIPSN Statement of vaccines and drugs in relation to COVID-19. Please carry this in your press/media**

P.Rajamanickam
General Secretary, AIPSN

A Network of 40 People's Science Movements working in 25 states

AIPSN Statement on Covid-19 Vaccines and Treatment Drugs

India must follow Transparent, Reliable, Scientific Clinical Trials Protocols

Development of vaccines and medicines that treat Covid-19 are extremely important elements in the ways to overcome the Covid-19 pandemic. Around 150 vaccine candidates are currently undergoing pre-clinical and clinical trials globally, though none are yet available. However urgent the need, this vaccine development must also ensure both efficacy and safety, otherwise it will endanger the efforts to overcome Covid-19 and also vaccine programmes against other infectious diseases.

Scientists working in the National Institute of Virology (NIV) under the ICMR and Hyderabad-based BBIL have developed an inactivated vaccine candidate, BBV152 COVID, using a virus strain isolated in NIV. BBIL got approval for Phase 1 and Phase 2 trials on June 29 from the Central Drugs and Standards Control Organisation (CDSCO) as part of the fast-tracking of the process even while pre-clinical animal trials are still underway. According to the submission of BBIL with the Clinical Trials Registry of India (CTRI) also under ICMR, the enrolment for Phase 1 was to begin from July 13th and the duration of the trial covering all the three stages was to be 15 months. 12 hospitals with widely varying track-record and experience in vaccine trials have been selected for the purpose by ICMR in an entirely arbitrary and non-transparent manner.

On July 2nd, Dr. Balram Bhargava, Director General, ICMR, who is also Secretary, Health Research in the government, sent a letter to BBIL with copies to the 12 chosen hospitals for the trials saying that “it is envisaged to launch the vaccine for public health use latest by August 15th, 2020,” that is in less than 6 weeks compared to the planned 15 months. The letter demands that subject enrolment be initiated no later than 7th July 2020, even though the CTRI registration itself shows July 13th as enrolment initiation, leaving no time for proper consideration and approval by the respective institutional ethics committees. Finally, the letter threatens these hospitals that “non-compliance will be viewed very seriously,” adding that the vaccine project is “being monitored at the top most level of the Government.”

Since “top most level of government” has been invoked, DG ICMR’s deadline appears for enabling the Prime Minister to announce “successful development of a Covid vaccine by India, before any other country,” from the ramparts of the Red Fort on Independence Day. However, as India’s premier scientific and medical research body, ICMR knows well the rigorous protocols required to be followed for vaccine trials, and therefore also that a deadline of 6 weeks to complete all three phases is scientifically absurd downright dangerous, and will cause serious damage to the reputation of Indian science and research. A desire to grandstand and please the political masters seems to have overtaken science and ethics within ICMR. AIPSN deplors the emerging trend in India of short-circuiting established protocols for trials of Covid19 vaccines and treatment drugs.

Earlier, there was the instance of Coronil, an ayurvedic mix sought to be launched for treatment of Covid-19 by the Patanjali group headed by Baba Ramdev, based on spurious, improperly conducted and assessed clinical trials. . After uproar by scientists and in the media, the AYUSH ministry prohibited Patanjali from selling or advertising Coronil as a treatment for Covid-19. However, nothing was done

about Patanjali not following due process of clinical trials and approvals. Glenmark obtained approval from DCGI for Covid19 treatment without any trials in India for manufacture of the antiviral drug Favipiravir. At a cost of Rs 103 a tablet and needing 122 tablets for a full course, the company stands to make a killing in profits. Highlighting the dangers of such hasty approvals without due process, the Lok Nayak Hospital in Delhi recently decided to stop using Favipiravir for Covid19 treatment following observations of problems in heart rate and uric acid levels in patients.

ICMR has also persisted with guidelines to administer Hydroxychloroquine (HCQ) to frontline health care workers and care-givers for patients in home isolation as a prophylactic. It is supposedly a 'trial' but without the strict protocols required for a trial. This despite published results of international trials showing lack of efficacy and possible adverse side-effects, and WHO guidelines against use of HCQ.

AIPSN demands that the due process of scientific trials be followed strictly and transparently for all Covid19 candidate vaccines and treatment drugs, regardless of systems of medicine, and overcoming temptations to make haste prompted either by corporate greed or false national pride.

AIPSN calls for a globally coordinated effort that puts people before profits to make drugs and vaccines that will be available free to the public and with allocations to countries made as per needs without any discrimination instead of the current perverted race to develop drugs and vaccines driven by jingoistic-nationalism and corporate profits.

AIPSN demands that the efforts of the scientists who came up with the BBV152 COVID vaccine candidate, or others likely to come up in the near future, not be wasted by such unseemly political pressures which compromise the safety of people by not following due process and which is highly likely to bring Indian science and research into disrepute.

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