

**ALL INDIA PEOPLE'S SCIENCE NETWORK (AIPSN)**

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15 Jan 2021

**Sub: AIPSN Statement on Vaccines Roll-out**

Please find attached the statement from AIPSN on “Vaccines Roll-out”

**AIPSN urges:**

- **The Union Government issue special protocols for Covaxin administration in “clinical trial mode,” including obtaining informed consent or refusal of recipients and ensuring compliance with all CDSCO/SEC approval conditions;**
- **CDSCO and ICMR to ensure that all clinical trials conform to necessary ethical, scientific and technical standards;**
- **All State Governments take a hard decision on whether to deploy Covaxin widely, or whether to strictly conform to CDSCO/SEC conditions of limited “trial mode” deployment;**
- **All doses of Covaxin distributed to States so far be held in stock by them and not administered till greater clarity is given by the Government or till CDSCO/SEC approval conditions are amended based on efficacy data from Bharat Biotech-ICMR as promised.**

General Secretary AIPSN

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

## **AIPSN Statement on Vaccines Roll-out**

**15 Jan 2021**

[All India Peoples Science Network \(AIPSN\)](#) is shocked that, as part of the mass vaccinations in India [beginning on 16 January 2021](#) with inoculation of health workers, the [Central Government is distributing 56 lakh doses of Bharat Biotech-ICMR's Covaxin](#), along with 110 lakh doses of Serum Institute of India-Oxford Astra Zeneca's Covishield. This is in open defiance of the conditions imposed by the Central Drugs Standards Control Organization (CDSCO) while [granting emergency approval for Covaxin](#). CDSCO and its Subject Expert Committee (SEC) had clearly differentiated between Covishield and Covaxin. Whereas both vaccines were approved for "restricted use in emergency situations," [Covaxin was given conditional approval](#), after apparent overnight arm-twisting of the SEC, only "[in clinical trial mode \(emphasis added\).](#)"

56 lakh doses, i.e. inoculation of 28 lakh persons, cannot be considered a "trial" by any stretch of the imagination, especially when Phase-3 clinical trials for Covaxin are already underway involving around 26,000 volunteers. Clearly, the Government has placed Covaxin and Covishield on similar footing, other than total numbers as of now. Any "trial mode" vaccination should involve special monitoring, follow-up and institutional arrangements. The ethical and scientific quality of the 'trials' cannot be disregarded. There is no information yet available in the public domain if the Government has communicated any special protocols for Covaxin inoculation. Most importantly, clinical trials should require informed consent or refusal by Covaxin recipients, after being made fully aware of conditions imposed by the CDSCO and the absence of Phase-III efficacy data.

In contrast, Secretary, Union Health Ministry stated in a press conference that [recipients would have no right to choose between the two vaccines](#), making it clear that the Central Government is intent on shoving Covaxin down the throats of State Governments and into the arms of innocent recipients, in this first round the health workers and "Covid heroes" regardless of the CDSCO conditions.

Government has only itself to blame if public suspicion about Covaxin and vaccine skepticism increases further due to its own complete opacity in rolling out Covaxin, with no information on any of the questions raised here. Unfortunately, the CDSCO and the Union Health Ministry, have subverted the scientific criteria regarding the regulation of vaccines including their own guidelines for emergency use. This would compromise both people's interests and the credibility of Indian pharma internationally. Bharat Biotech CEO's unseemly attack on people who have criticized the government's clearance on emergency use of its vaccine and attacking other vaccines does not add any credibility to its vaccine.

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- *CDSCO and ICMR to ensure that all clinical trials conform to necessary ethical, scientific and technical standards;*
- *All State Governments take a hard decision on whether to deploy Covaxin widely, or whether to strictly conform to CDSCO/SEC conditions of limited “trial mode” deployment;*
- *All doses of Covaxin distributed to States so far be held in stock by them and not administered till greater clarity is given by the Government or till CDSCO/SEC approval conditions are amended [based on efficacy data from Bharat Biotech-ICMR as promised.](#)*

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