AIPSN Statement

29 Sept 2021

WHO refusal of Emergency Use Approval for Covaxin

All India Peoples Science Network (AIPSN) notes with sorrow and grave concern that the World Health Organization (WHO) has not granted Emergency Use Listing (EUL) for ICMR-Bharat Biotech's (BB) Covaxin vaccine, but has asked BB for more technical details. This is a serious setback for Covaxin and for India's vaccination programme in the country, and a blow to India's plans to distribute vaccines to other countries. Many Indians traveling abroad, especially students, who took Covaxin, are already finding it difficult to obtain visas or entry into other countries which generally recognize only WHO-approved vaccines. This sorry state of affairs will continue as long as there is no public accountability, transparency along with scientific rigour.

Covaxin will also once again face vaccine hesitancy in India as it did during the earlier controversial approvals process. AIPSN had earlier urged the public disclosure of trial data and now mourns the serious damage done to the reputation of India by this flawed application to WHO regulators, which has also besmirched the standing of Indian science and regulatory systems, which will now come under heightened international scrutiny and suspicion.

Unfortunately, this was entirely foreseeable. BB has played ducks-and-drakes with regard to transparency of clinical trials data and respect for regulatory processes and institutions. In December 2020/January 2021, BB applied to the Indian regulator, DCGI for EUA with grossly inadequate data from clinical trials inviting rejection, followed by behind-the-scenes arm-twisting by the Union Government resulting in grant of EUA. More detailed results of Phase-3 clinical trials were then released by BB in installments, interim results two months later and complete trial data in June 2021. Despite much criticism from scientists and others in India, including by AIPSN, BB has regrettably not published these results in a peer-reviewed journal even to date, but has only posted a pre-publication paper. BB could get away with all this because of the open backing of the Union Government which echoed all excuses and justifications put forward by BB, such as saying in June 2021 that BB would publish results in a few weeks, and even recently announced that it was expecting WHO approval soon. Criticism of this chain of events, and calls for greater transparency on clinical trial data by BB and also by its governmental partner ICMR, in the interests of Indian science and its international reputation, were attacked by the Government as anti-national and undermining the prestige of India and its scientists. The chickens have come home to roost with WHO's refusal of EUL for Covaxin.

Compounding these errors of judgment by the Government and by DCGI bending to its will, India looks set to repeat these blunders in the approvals process for Zydus Cadilla's ZyCov-D 3-dose Covid vaccine for those 12 years or older. Zydus had applied for EUA on 1st July 2021 based on interim data and obtained it on 20th August. However, this interim data has not been made public or published anywhere, even in pre-print form, raising the same concerns and criticisms as with Covaxin. Covaxin was one of the first Covid vaccines developed by a middle-income, and would have indeed boosted India's prestige if it had obtained approvals in India and abroad with transparent and published peer-reviewed data. ZyCov-D too would similarly have enhanced India's image as the only one of just 11 DNA-based vaccine candidates worldwide. Regrettably, the powers that be seem to have decided to follow a non-transparent government-ordered vaccine approval process that achieves precisely the opposite. As is said history repeats itself "First as tragedy and second time as farce".

All India Peoples Science Network (AIPSN) urges the Government of India, its concerned ministries, departments, institutions and authorities *of the need to adhere to scientific standards for conduct and analysis of clinical trial results, publication of results as peer-reviewed articles and complete transparency. Regulatory agencies should also assert their independence from both government and corporate interests, and make judgments based on scientific analysis.* Vaccine producers must build transparency in this regard, while fulfilling their responsibilities and accountability. We need to ensure that urgent approval of vaccines, publication of clinical trial data and the safety and efficacy of the vaccine all receive equal and due importance.

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