Biotechnology

Experts advocate need to assess risk profile of vaccines for COVID-19 amidst WHO disapproving Russian vaccine due to lack of clinical data

Shardul Nautiyal, Mumbai
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Experts have cautioned the government about the need to assess risk profile of vaccines for COVID-19 amidst reports of World Health Organization (WHO) recently disapproving Russian vaccine 'Sputnik V' for COVID-19 due to lack of clinical data or evidence. History has proven time and again that vaccine trials and manufacturing must be handled with extreme caution to avoid infecting recipients or causing severe adverse effects, they say.

"Whenever there is a discussion of vaccine trials, the infamous 'Cutter Incident' comes to mind which resulted in a major disaster Around 40,000 children developed mild polio, 200 were permanently paralyzed and 10 children died. The incidence occurred due to a defective virulent strain of polio which was used in the development of vaccine causing paralysis and death," according to Dr Nitin Malekar, Geneticist and Healthcare Communication Professional.

Russia on August 11, 2020 had launched the COVID-19 vaccine, described by President Vladimir Putin as the world's first. According to WHO, there are six vaccine candidates in phase 3 or phase 2 to 3 combined trials around the world and roughly another 120 in various stages of clinical testing. Vaccine trials are primarily conducted to examine toxicity, immunogenicity, and serious adverse effects (SAEs) of the vaccine agent. The vaccine must pass all the three stages of trial and prove to be safe and effective in target disease conditions before it is sent for regulatory clearance and after approval for the mass production.

The four-stage research study including the 4th stage of market surveillance is essential to gather precise information about the usage, adverse effects, and long-term immunity. Vaccine trials may take months or years to complete since a specific incubation period is necessary to react to the vaccine and develop the required antibodies. For most of the vaccines, single-dose administration is not sufficient to study the immune response, over-all immunity protection and long-term efficacy of the immune response which may eventually require booster doses.

"Once vaccine reaches the market, the important aspect is 'adverse effects', which may not get triggered by the first dose of vaccine but might get triggered or will become evident at the time of booster vaccination. In scientific language, these incidents are known as positive re-exposure," mentioned Dr Malekar.

'WHO' and partners have included nine experimental COVID-19 vaccines within an investment mechanism known as the Covax facility.

Talking with reference to tocilizumab which failed in phase III clinical trial recently, the drug which was lately promoted as an effective treatment in severe cases of COVID-19 to calm cytokine storm and reduce mortality, Ahmedabad based pharma consultant Dr Sanjay Agrawal argued, "There are absolutely no admissible clinical trials which can show clear evidence that tocilizumab is safe and effective for addressing COVID-19 cases. How regulators have permitted its off-label use and such kind of promotion by bypassing important phase III clinical trials is a serious question. Now the drug, having failed in phase III clinical trials, has also upset patients and the medical fraternity alike."

Echoing similar views pharma consultant Anshu Yadav pinpointed, "Tocilizumab had recently emerged as an alternative therapy for COVID-19 on randomized controlled trial and now did not meet its primary and secondary endpoint of improved clinical status in patients with COVID-19 casting aspersions on its safety and efficacy. In the recent phase III trial, it did not reduce severe respiratory symptoms, intensive care or death compared with standard care. Surprisingly, it is recommended by ICMR for emergency use. This hit and trial measure may cause more harm than good."

The most advanced potential vaccine candidates which have recently moved into clinical development include mRNA-1273 from US-based biotechnology company Moderna, Ad5-nCoV from Chinese biopharma company CanSino Biologicals and INO-4800 from American pharmaceuticals company Inovio. Others in the list include LV-SMENP-DC and pathogen-specific aAPC from Shenzhen Geno –Immune Medical Institute in China.

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