Volunteer falling sick hasn't affected Serum trials: Govt

Vaccination not needed for whole country: Health min

Union Health Secretary Rajesh Bhushan on Tuesday said the government had never planned for vaccinating the whole country against coronavirus, but just enough to stop the chain of transmission.

Balram Bhargava, director general, Indian Council of Medical Research, said: "If we are able to vaccinate a critical mass of the people and break the transmission we may not have to vaccinate the entire population."

With the recent adverse event surrounding one of the top vaccine candidates, leading to fears about its safety, Bhushan said it was the collective responsibility of the Centre and the state governments, along with the companies, to educate the people on the safety and effectiveness of the trials.

The ministry is planning to issue guidelines that will address issues on vaccine safety.

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The adverse occurrences surrounding a volunteer falling sick in the Covid vaccine trials by Serum Institute of India (SII) have not interrupted work or affected the time frame of Covishield's rollout plans, government officials said on Tuesday.

As thousands of individuals across the world help the scientific community find a vaccine, even at a certain risk to themselves, the recent controversy has sent jitters among not just the public but also volunteers, who could question what it is that they are signing up for.

While Union Health Secretary Rajesh Bhushan, addressing queries in media briefing on Covid situation, said due processes were followed by SII in reporting the event, he also reiterated that the volunteers signed a prior consent form, which warned them of possible adverse effects.

The amount of compensation depends on whether the injury is permanent or not

Under the New Drugs and Clinical Trials Rules 2019, an informed consent has to be recorded on video. Experts say the volunteer signs the consent form with the assurance that the vaccine and the placebo are both reasonably safe except that they may cause fever, pain at the time of the injection, headache, or body ache, which may last a short period of time.

"The investigator guarantees that there will be no risk to life. The risks of serious to adverse reactions are not known." said Jacob John, former head of the Indian Council of Medical Research's Centre for Advanced Research in Virology.

According to experts, India is one of the few countries that have a compensation mechanism in the case of an injury or the death of the volunteers during a trial.

The amount of compensation depends on whether the injury is permanent or not.

If the sponsor fails to provide compensation, the trial can be cancelled and the central licensing authority can take action.

"While volunteers have the option to opt out at any point without giving a reason, they have the legal right to get all information on the trials," said Dr Chirag Trivedi, president, Indian Society for Clinical Research.

The law also lays down clear protocols to not just report an adverse event but also ensure independent monitoring.

The Institutional Ethics Committee, which is independent of government, has to submit its report within 30 days of the adverse event to the Drug Controller General of India, the regulator.

This committee has at least seven members including a legal expert and an independent person from any other related field such as a social scientist or from an NGO. The committee also approves protocols to ensure that risk to volunteers is minimum.

There is also the Data Safety Monitoring Board (DSMB), comprising domain knowledge experts from outside government and the vaccine-manufacturing company. It keeps an eye on trials on a daily basis and any adverse event that might occur. The board gives its findings to the regulator, in case there is an adverse event.

"It is the DSMB which has the code for the dose that a volunteer is receiving. The code determines whether the participant received a placebo or the vaccine," John said. He also said the trial had to be insured for health and life.

Based on the scientific data, the regulator has to ascertain whether there is a one-to-one correlation between the vaccination and the adverse event. Accordingly, a decision is taken whether to halt or cancel the trial.

During polio vaccine trials, many patients were infected with the virus. "In the US it led to millions of dollars being given in compensation ... Later it also helped discover a much more effective vaccine for polio," John added.

In the case of coronavirus vaccine trials in India, the first adverse event was reported during Phase One of Bharat Biotech's Covaxin. That was ascertained as not being vaccine-related.

Experts said a trial may not be halted if the adverse event is not serious or unrelated to the vaccine.