

LITTLE RECOURSE FOR PEOPLE WHO ARE HARMED BY COVID VACCINES

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With the government not taking responsibility and a compensation law non-existent, anyone suffering a major side-effect after receiving the coronavirus [vaccine](#) may be left with no option but to try and sue authorities and companies, experts said.

To be sure, a serious adverse event (SAE) is a rare occurrence.

"We don't have a systematic policy on compensation in case a person gets harmed by a [vaccine](#). If anybody either gets injured by it or dies, there are only two ways compensation is likely to be given: they either have to go to court, or they have to politicize the issue until the government gives an ex gratia amount to them," said Amar Jesani, editor of the Indian Journal of Medical Ethics.

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In the case of Bharat Biotech International, there is a possibility of getting compensation under clinical trial norms as its vaccine, Covaxin, has received an emergency licence from the Drugs Controller General of India under a 'clinical trial mode'. Under clinical trial rules 2019, a person injured during a study can claim compensation if the drug is found to be the cause of the side-effect. However, even in the case of Covaxin, experts said there is no clarity from the government or the drugs regulator.

"Since Bharat Biotech has got an authorization in 'clinical trial mode', there may be a possibility to get compensation under the law, but this is also 90% guesswork because the regulator and the government have not described what 'clinical trial mode' means," said Anand Grover, a senior advocate.

For Serum Institute's Covishield, there is no other legal remedy to receive compensation other than a court case, but it would be a long and arduous process, Grover said.

He pointed to the poor record that India has in paying compensation for injuries. The most prominent example for that is for victims of the Bhopal gas tragedy of 1984, many of whom are yet to be fully compensated after 34 years. Also, even if the government holds the company responsible for compensation, there is no law supporting such compensation.

Meanwhile, the two vaccine makers have sought indemnity from the government, which means if there is a serious side-effect, the government will be held liable to pay for it. While this could potentially make it easier to seek compensation, experts said the lack of clarity on the subject and whether there will be a 'no-fault compensation' need to be looked at. In a no-fault compensation, a panel set up to review an injury or death does not look at whether the drug or any other factor has caused the side-effect. It simply determines the compensation based on the person's age, earnings, and severity of the injury, among other factors.

However, even before the matter of compensation comes up, there is the issue of reporting the serious side-effect, said senior advocate Colin Gonsalves.

Often, people who are vaccinated are not told who they should contact in case of a serious

adverse effect. Covishield's fact sheet states if there is a severe allergic reaction to the vaccine, the person should go to the nearest hospital and also call its 24x7 toll-free number (1800 1200 124) or write to pharmacovigilance@seruminstitute.com.

However, Gonsalves said, vaccine beneficiaries might not get this information as it is likely to be kept with the hospital. "Going to courts is the last stage. How do you go to courts if you do not know whom to report the serious side-effect to?" he said.

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