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Who pays compensation if a COVID-19 vaccine has rare side-effects?

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What does Australia's latest indemnity deal mean in practice?

To encourage people to receive COVID-19 vaccines for the benefit of the entire community, we need compensation schemes to be in place if there is a rare but serious side-effect, writes Associate Professor Nicholas Wood.

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In last week's federal budget the Australian government announced it had given the suppliers of two COVID-19 vaccines indemnity against liability for rare side-effects.

Although details are unclear, it appears the government would foot the bill for compensation if a member of the public wins legal action against the drug company.

This is in contrast to 25 other countries with no-fault compensation schemes for rare vaccine side-effects.

Here's the little we know about Australia's latest indemnity deal and what we could be doing better.

What do we know about Australia's new deal?

The deal relates to two vaccines the government had previously announced it would supply, should clinical trials prove successful.

These are the University of Oxford vaccine, from AstraZeneca, and the University of Queensland vaccine, from Seqirus (part of CSL).

However, it is not entirely clear what this indemnity deal means in practice. The budget papers say the government will cover: *'certain liabilities that could result from the use of the vaccine.'*

The government considers further details "commercial in confidence".

For instance, we don't know how serious or disabling a side-effect would have to be to qualify or whether there is any cap on the amount of compensation.

We also don't know what would happen if there were errors involved, or contaminants introduced, while manufacturing the vaccine. These would still be the company's liability, but it may be hard to determine where boundaries lie.

How unusual is this?

This deal is not entirely new or unexpected. The government has provided some indemnity to pharmaceutical companies that make vaccines against smallpox and influenza.

The governments of many other countries have also agreed to indemnify COVID-19 vaccine manufacturers, including governments in the UK, US and the European Union.

The manufacturers believe that as the use of their vaccine is for the benefit of society, they should not be held financially accountable for any consequences from a vaccine reaction.

So what does this mean for the public?

If a person in Australia believes they have been injured by a vaccine, including future COVID-19 vaccines, they will need to pursue compensation through the legal system.

Under the latest agreement, it would appear the government, rather than the drug company, would pay that compensation, should the person win their case.

However this is not ideal. The person still has to engage with the legal system, which is both costly and complex, and there's no guarantee of success.

Compensation may not even be possible via our legal system. That's because in most cases, it will be difficult to show in court a serious side-effect was due to a fault in the vaccine composition or negligence in the way it was administered.

So in Australia, people with a vaccine injury, either COVID-19 or other vaccine, will likely bear the costs of their injury by themselves, and seek treatment by our publicly-funded or private health systems.

The National Disability Insurance Scheme helps fund therapies for people with a permanent and significant disability but does not cover temporary vaccine-related injuries.

Participants in COVID-19 vaccine clinical trials can be compensated for temporary and permanent vaccine injuries.

What's happening overseas?

In the US, people with a rare but serious reaction to a COVID-19 vaccine will be able to access a special compensation scheme. This is designed to provide compensation for the use of COVID-19 pandemic medications and vaccines.

However, applicants only have one year from the date they had the vaccine or medicine to request benefits.

The US already has a vaccine compensation scheme for vaccines other than COVID-19. This is an example of a no-fault compensation scheme. These compensate for specific vaccine reactions, without having to go to court to prove the vaccine manufacturer is liable.

Australia, in contrast to 25 countries including the US, UK and New Zealand, does not have a no-fault vaccine compensation scheme, and does not have the equivalent of the US COVID-19 vaccine compensation scheme.

How would a no-fault system work?

There are numerous benefits to a no-fault vaccine compensation system. These include simplified access to compensation, and avoiding a lengthy, costly and complex encounter with the legal system, with no guarantee of success.

Most are government funded. The US government funds it by a flat rate of US$0.75 for each disease prevented for each vaccine dose.

Finland and Sweden fund their programs via insurance payments from pharmaceutical companies marketing their products there.

The New Zealand scheme includes compensation for vaccine-related injuries, as well as for accidents and treatment injuries. This is funded through a combination of general taxation, and levies collected from employee earnings, businesses, vehicle licensing and fuel.

However, compensation awarded via such no-fault schemes is usually lower than you would receive after a successful liability lawsuit.

Where to next?

To encourage people to receive COVID-19 vaccines for the benefit of the entire community, we need compensation schemes to be in place if there is a rare but serious side-effect.

Should options to increase vaccine uptake include mandates or penalties — such as employment or travel restrictions if not vaccinated — this would make a no-fault vaccine compensation scheme even more essential.

Although it is important manufacturers receive indemnity for "certain liabilities", we still need to look after our community. That means a compensation system the public can easily access and which provides appropriate support.

This article was first published on The Conversation. It was written by Associate Professor Nicholas Wood, Faculty of Medicine and Health at the University of Sydney.

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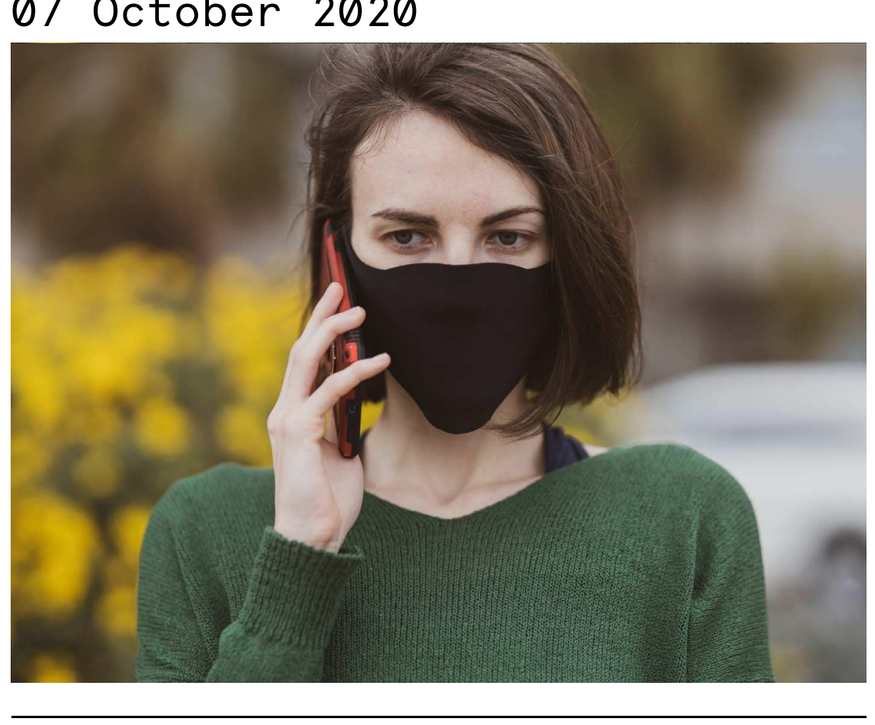

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