

As Australians Seek Compensation for Vaccine Injuries Under New Plan, Here's a Look at COVID Vaccine Liability Laws Around the World

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More than 10,000 Australians so far requested compensation for COVID vaccine injuries under the country's vaccine injury compensation scheme. What types of compensation programs exist in other countries?

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Recent [reports](#) from Australia indicate more than 10,000 Australians are requesting compensation for vaccine injuries that they received following inoculation with the [COVID-19](#) vaccine.

The claims come as part of an Australian [government program](#) allowing individuals to be compensated for lost income after being hospitalized for "rare but significant" side effects resulting from the vaccination.

As originally conceived, compensation through the program was

available to people who incurred A\$5,000 or more in vaccine injury-related medical costs. However, the government enacted a [reduction](#) in the compensation threshold, permitting claims for the cost of vaccine injuries beginning at A\$1,000.

The 10,000-plus compensation claims were submitted as almost 79,000 adverse side effects after COVID vaccines were reported to the country's [Therapeutic Goods Administration](#), as of mid-November.

No-fault vaccine liability: what is it?

Australia's vaccine injury compensation program is an example of a "no-fault compensation program."

This [refers to](#) a measure put in place by public health authorities, private insurance companies, manufacturers, and/or other stakeholders to compensate individuals harmed by vaccines. [Such programs](#) allow a person who has sustained a vaccine injury to be compensated financially, without having to attribute fault or error to a specific manufacturer or individual.

No-fault compensation schemes are one of [three options](#) used by various countries to handle vaccine injury claims.

The other two options include allowing vaccine-injured people to sue private-sector actors, such as vaccine manufacturers or their insurers, or to place the full financial burden on the patient.

Australia's no-fault compensation program is fairly new. It was [launched](#) in August 2021, despite longstanding [calls](#) for the development of such a scheme well before COVID.

[A 2020 study](#) found 25 countries with a no-fault program in place, with 15 of these programs administered at the government level.

In some countries, such programs are administered at the

provincial level or at multiple levels of government, while two countries (Sweden and Finland) were identified by the study as having no-fault programs fully administered by the insurance sector.

The exact nature of such no-fault schemes, however, can differ significantly from one country to another. As explained in the 2020 study:

- In Sweden and Finland, pharmaceutical companies who market their products in these jurisdictions provide insurance contributions which fund those countries' no-fault programs.
- Similarly, Norway's no-fault program is funded by a special insurance organization known as the Drug Liability Association.
- Latvia's Treatment Risk Fund is funded through contributions from medical institutions, acting as professional indemnity insurance.
- In China and South Korea, there are two separate programs, covering those vaccines in each country's national immunization program (NIP) and those not included in the respective country's NIP. Each government funds injury claims for NIP vaccines, while pharmaceutical companies or those holding a drug's market authorization are responsible for funding injury claims regarding non-NIP vaccines.
- The U.S. no-fault [Vaccine Injury Compensation Program](#) is funded by a flat-rate tax of 75 cents for each disease covered in each vaccine dose.
- New Zealand has set up an Accident Compensation Corporation, which acts as a general compensation fund for accidents stemming from vaccinations, and treatment injuries. The program is funded through general tax contributions and levies on employee wages, businesses, vehicle licenses and fuel sales.

Not all no-fault programs compensate for injuries arising from

all vaccines. For instance, according to the 2020 study:

- Only five (Japan, France, Italy, Hungary, and Slovenia) of the 23 programs specifically examined by the study covered injuries arising from mandatory vaccines or vaccines recommended by law – of particular significance in a world where more and more countries are attempting to implement COVID vaccine mandates.
- Just over half (57%) of the programs examined provide compensation for injuries arising from registered and recommended vaccines for children, pregnant women or adults and for special indication, such as occupation or travel, within the jurisdiction. This latter point is also significant in an era where many COVID vaccine mandates are being imposed on specific occupations or as a means of being “allowed” to travel.

Different no-fault programs also have differing rules with regard to when claims can be filed.

Referring again to the 2020 study, in certain countries, claims have to be filed within a certain number of years of vaccination or, in some cases, of the initial onset of vaccine injury symptoms. This ranges from 20 years (Norway), to six years (UK, for adults), to three years (U.S. and several other countries).

In some other countries, the maximum interval varies by province (China), or there is no specific deadline for filing a claim (including Sweden, Germany, New Zealand and Japan for NIP vaccines).

As seen with the example of Australia above, no-fault programs also set compensation thresholds. This is true in all no-fault countries examined by the 2020 study.

Thresholds of eligibility also exist, which may include injuries resulting in financial loss or permanent or significant injury (such as a medical disability), serious

health damage or death, severe injuries surpassing normal post-vaccination reactions or other degrees of injury.

Just over half (52%) of the programs studied also provided compensation for claims regarding vaccine defects or immunization errors, while in the remaining countries, these types of claims are covered separately, through civil litigation or medical malpractice indemnity.

The 2020 study also noted that in almost all no-fault jurisdictions, such programs are non-judicial in nature and are instead administrative in scope, typically involving panels of medical experts who review each individual vaccine injury claim.

In a minority of countries, the administrative program is combined with a legal approach and the involvement of legal experts, while in Finland and Sweden, compensation decisions are made based on civil liability (tort) laws.

The standard of proof the claimant is required to demonstrate is generally similar across most no-fault programs, according to the 2020 study. These programs tend to employ a “balance of probabilities” approach that weighs whether it is “more likely than not” that the vaccination led to the injury in question.

This approach takes into consideration such factors as the time interval since vaccination, and existing medical evidence establishing a connection between the vaccine and that type of injury.

A country-by-country look

The above provides a general overview of how no-fault compensation programs work. However, it is also worth examining the specific rules in place in major countries and blocs of nations around the world.

United States:

In 1986, the U.S. Congress passed the [National Childhood Vaccine Injury Act of 1986](#), often simply referred to as the Vaccine Act. Under this act, a no-fault program for administering vaccine claims, known as the [National Vaccine Injury Compensation Program](#) (VICP) was established.

Through this program, any individual claiming a vaccine injury (or a parent or guardian of a child) can file a petition with the U.S. Court of Federal Claims. The petition is reviewed by the U.S. Department of Health and Human Services (HHS), which makes a preliminary recommendation.

The U.S. Department of Justice (DOJ) then prepares a legal report, which includes the medical recommendation, and submits it to the court. The court then appoints a special master, who may convene a hearing, and who decides whether the petitioner should be compensated, and if so, what the level of compensation will be.

This compensation is then disbursed to the petitioner through HHS. Petitioners may also appeal a decision that isn't in their favor, and by rejecting the decision of the court, may then file a lawsuit in civil court against the vaccine maker and/or the healthcare provider who administered the vaccine.

VICP, however, does not encompass all vaccines. It [covers](#) vaccines that are routinely administered to children and to pregnant women, and that are subject to the previously-mentioned 75-cent excise tax.

To date, more than 8,400 VICP claims have been [settled](#), out of more than 24,000 petitions, with a total of \$4.6 billion issued in settlements.

Compensation has also been issued. However, most such settlements were reached following negotiations instead of a hearing, with no admission on the part of HHS that vaccines were ultimately responsible for the injuries in question.

A different category of vaccines, including, at present, the existing COVID-19 vaccines, are covered under what is known as the [Countermeasures Injury Compensation Program](#) (CICP).

This program was established under the aegis of the [Public Readiness and Emergency Preparedness \(PREP\) Act](#) of 2005. The PREP act was developed to coordinate the response to a “public health emergency.” The law is scheduled to remain in place until 2024.

CICP specifically focuses on countermeasures, that is, “a vaccination, medication, device or other item recommended to diagnose, prevent or treat a declared pandemic, epidemic or security threat.”

Under CICP, a different [claims process](#) exists as compared to the VICP. The process for claimants is more cumbersome, and individuals have only one year after the administration of the vaccine to file a claim. Injuries whose symptoms materialize later in life, for instance, would presumably not be covered under this process.

Moreover, the likelihood of success, if past precedent is any indication, is slim. As [previously reported by The Defender](#):

“The program’s parsimonious administrators have compensated [under 4% of petitioners](#) to date – and not a single COVID vaccine injury – despite the fact that physicians, families and injured vaccine recipients have reported more than [600,000 COVID vaccine injuries](#).”

Notably, vaccines with full FDA approval but which are not placed on a vaccination schedule for children or pregnant women are [subject to](#) ordinary product liability laws, while vaccines administered under an [Emergency Use Authorization](#) are protected from legal liability.

Furthermore, a 2011 [Supreme Court decision](#), *Bruesewitz v. Wyeth*, held that the Vaccine Act preempts claims made under

state-designed defect laws, against vaccines covered by the Act. The decision [stated](#) that “[The Vaccine Act] reflects a sensible choice to leave complex epidemiological judgments about vaccine design to the FDA and the National Vaccine Program rather than juries.”

Until the 1980s, a series of successful lawsuits against vaccine makers was [seen](#) as resulting in increasing vaccine hesitancy and declining vaccination rates, as indicated in a 1985 National Research Council [publication](#), released just one year before the passage of the Vaccine Act.

Canada:

In recent years, Canada was the [only](#) G7 country without a nationwide no-fault vaccine injury compensation program. On a provincial level, Quebec established such a program in 1985, at which time [calls](#) for the creation of a national program followed. [Attempts](#) were made to develop a national program at this time, which ultimately failed.

As of 2018, Quebec’s program had [approved](#) a total of 43 claims, paying \$5.49 million (CAD) in compensation.

In June 2021, [launched](#) a national vaccine injury compensation program, the [Vaccine Injury Support Program](#). The program covers all provinces except Quebec, whose provincial program will continue to operate.

While this program is funded by Public Health Canada, it is administered by a private company, RCGT Consulting.

The program [covers](#) claimants who received a Health Canada-authorized vaccine (on or after Dec. 8, 2020), administered in Canada, with a resulting injury that is serious and permanent or which has resulted in death, and which was reported to the healthcare provider that administered the vaccine.

Though it wasn’t until a few months ago that Canada was able

to establish a nationwide vaccine compensation program, COVID vaccine manufacturers were already, as of December 2020, [indemnified](#) against claims of vaccine injuries.

United Kingdom:

In the UK, the [Vaccine Damage Payment Scheme](#) (VDPS) provides compensation totaling £120,000 to anyone who suffers a disability of 60% or more, as a result of their vaccination.

The percentage figure refers to a [severe disability](#) resulting in such injuries as the loss of a limb, an amputation, losing 60% or more of normal vision or severe narcolepsy.

Additionally, the 1987 [Consumer Protection Act](#) also applies to those who have sustained a vaccine injury, if it is [found](#) that the product in question did not meet safety standards or was defective. This is further strengthened by the 2005 [General Product Safety Regulations](#).

Consumer protection rights still apply for people injured by the COVID vaccine, as the government wasn't allowed to take those away. But due to the legal definition of defects, and a rule known as the state-of-the-art defense, it is difficult to get compensation when specific problems with the vaccine are not yet known.

COVID vaccines have been added to the VDPS. However, according to the [Human Medicines Regulation of 2012](#), protection against civil liability is provided to vaccine manufacturers for unlicensed products issued under a temporary use authorization by the Medicines and Healthcare Products Regulatory Agency.

This regulation was further amended by the [Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020](#), providing extended immunity from civil liability to vaccine makers and those administering vaccinations. However, the consumer protection laws mentioned above still apply.

Legal indemnity has also been [directly provided](#) to vaccine manufacturers in the case of the COVID-19 vaccine.

European Union:

The UK laws are based largely on EU legislation, which was codified into British law prior to Brexit.

For instance, the UK Human Medicines Regulations of 2012 and 2020 are largely based on their EU equivalent, [EU Directive 2001/83/EC](#) relating to medicinal products for human use. This includes protections against civil actions for products released under temporary or emergency authorizations.

The 1987 Consumer Protection Act in the UK is, in turn, equivalent to the EU's [Directive 85/374/ECC](#) of 1985, on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, while the 2005 General Product Safety Regulations were harmonized with [EU Directive 2001/95/EC](#) on general product safety.

At the EU level, immunity for vaccine manufacturers was not standard prior to COVID, when legal responsibility [tended](#) to lie with the companies.

This, however, is not the case with the COVID vaccines. Under [pressure](#) from Vaccines Europe, a trade organization representing vaccine manufacturers in the EU, and under the guide of “ensuring access” to vaccines, [exemptions](#) from liability were granted to companies such as AstraZeneca.

Notably, a [question](#) posed in August to the European Parliament by one of its elected representatives, Ivan Vilibor Sinčić of Croatia, regarding liability for COVID-19 vaccine side effects, remains unanswered as of this writing.

Within the EU, different member states have enacted their own legislation with regard to vaccine injury compensation claims.

These programs were summarized in a [2021 study](#) examining such policies on a global basis. They can be summarized as follows:

- **Austria:** The Vaccine Damage Act is a public-law system for the payment of compensation for vaccine injuries by the state. COVID vaccines are included in this program.
- **Belgium:** No vaccine compensation legislation exists.
- **France:** The existing vaccine injury compensation program provides relief only for injuries related to mandatory vaccinations. Claims for injuries resulting from non-compulsory vaccinations fall under the general principles of French civil law. For COVID vaccines, claims can be lodged with the National Office for Compensation of Medical Accidents, without having to prove a defect with the vaccine or fault on the part of healthcare providers.
- **Germany:** A flat-rate no-fault compensation program exists for vaccines that are mandatory or that are publicly recommended, including COVID vaccines.
- **Greece:** A no-fault program doesn't exist, but a May 2021 [high court ruling](#) held that those who sustained vaccine injuries are entitled to state compensation.
- **Italy:** A no-fault program providing state compensation for injuries stemming from required or highly recommended vaccines exists, although it is unclear if this extends to COVID vaccines. Claimants are also free to pursue claims under tort law.
- **Netherlands, Portugal:** There is no specific no-fault scheme, but vaccine injury claims can be filed via provisions of the civil code.
- **Sweden:** An insurance fund, Swedish Pharmaceutical Insurance, handles vaccine injury claims out of court. However, new legislation which took effect Dec. 1 will provide additional state compensation for injuries arising from COVID-19 vaccinations.

Israel:

In Israel, the [Vaccine Injury Compensation Law](#) was passed in 1989, providing compensation to those injured by vaccines, without having to prove negligence.

Earlier this year, COVID-19 vaccines were included under this law.

New Zealand:

New Zealand [maintains](#) a no-fault system for accident compensation, including vaccine injuries, under the aegis of the previously-mentioned [Accident Compensation Corporation](#) (ACC).

Although most information on claims appears to be classified, financial compensation totaling \$1.6 million (NZD) was provided between 2005 and 2019.

The ACC also [handles claims](#) related to COVID-19 vaccination.

China:

China's vaccination program differentiates between mandatory and non-mandatory vaccinations, for the purposes of vaccine injury claims.

The 2019 [Law on Vaccine Administration](#) establishes a compensation system for deaths or significant injuries, such as organ or tissue damage, stemming from vaccines. Compensation is paid from the vaccination funds of the country's provincial governments.

Draft legislation in 2020 called for [mandatory liability insurance](#) for vaccine manufacturers distributing vaccines in mainland China. However, it is unclear if this legislation was enacted.

Japan:

Until recently, Japan did not have a specific no-fault

compensation program for vaccine injuries. But [temporary programs](#) where the government would provide compensation to vaccine makers for legal claims they sustained due to vaccine injuries had previously been passed in 2009, for the H1N1 vaccine, and again in 2011 until 2016.

However, a [2020 amendment](#) to Japan's Immunization Act now allows the government to take on the liability risks for COVID-19 vaccines.

India:

India has [no specific no-fault legislation](#) under the Drugs and Cosmetic Act for injuries stemming from vaccines that are fully licensed by the country's regulator.

Claimants are, however, able to file claims in consumer courts or in India's High Court, and the country's drug regulator can also take action against vaccine manufacturers for violations of the law.

Indian law does [provide](#) for compensation in the event of injury or death following participation in clinical trials.

Notably, the Indian government's negotiations with Pfizer fell through earlier this year when Indian regulators [refused](#) to provide it legal protection via indemnity.

Such protection was not provided to the three COVID-19 vaccines which received an emergency use authorization in India: Covishield, Covaxin and Sputnik V.

Adar Poonawalla, the head of the India-based Serum Institute, the world's largest vaccine manufacturer, had previously [called](#) for protection from lawsuits for COVID vaccine injuries.

Malaysia and Singapore:

The country has not developed a no-fault vaccination

program, [unlike](#) nearby Singapore.

Instead, a variety of legal [remedies](#) exist for claimants under civil law, including the Sales of Goods Act of 1957, the Consumer Protection Act of 1999, and the Contracts Act of 1950, and under criminal law, including the Poisons Act of 1952 and the Sale of Drugs Act of 1952.

South Africa:

South Africa is another country that did not develop a no-fault vaccine injury compensation fund until recently, but did so as a result of COVID and, apparently, [pressure](#) from vaccine manufacturers.

The fund is meant to provide compensation for “serious adverse responses” which lead to “permanent or significant injury, serious harm to a person’s health, other damage or death,” assuming these injuries were caused by vaccination.

Philippines:

Similar to South Africa, the Philippines only [recently](#) set up a no-fault indemnity program, shielding vaccine manufacturers, as well as public officials, from lawsuits, except in instances of gross negligence or willful misconduct.

This same program will also set up a state fund to provide compensation for vaccine injury claims.

Developing world:

Finally, for 92 low- and middle-income countries, the World Health Organization (WHO), along with a private company, Chubb Limited, has [begun to administer](#) a no-fault compensation program.

The countries in question are receiving COVID vaccines via the Gavi Alliance’s COVAX [Advanced Market Commitment](#) (AMC) program, with vaccine injury [claims](#) processed through the

WHO's new program, which is set to remain in effect until June 30, 2022.

No-fault schemes are increasing, but questions remain

With the recent examples of countries such as Canada and Australia, as well as South Africa and the Philippines, developing their own no-fault vaccine injury compensation funds, as well as their further extension to 92 low- and middle-income countries via the WHO, this type of compensation scheme is clearly the predominant method of dealing with financial claims stemming from vaccine injury claims.

As seen in the case of the U.S., such no-fault programs were developed to address claims of increased vaccine hesitancy, as a result of high-profile lawsuits against vaccine makers, and a decline in vaccine production from hesitant pharmaceutical companies which did not want to shoulder the legal and financial risks involved with releasing a new vaccine to the public.

What, however, goes unaddressed in such claims is the vaccine hesitancy, or outright refusals to get vaccinated, as people question why vaccine makers and, in many cases, everyone involved in distributing and administering vaccines, are shielded from legal action.

Such legal shields cast, for some people at least, a net of doubt, calling into question the safety of such vaccines if their manufacturers, distributors, and public health officials involved in their administration feel the need for legal protections. They may wonder why a product that is said to be safe requires such legal shields.

Such doubts further increase when governments and their agencies, which are essentially acting as guarantors of these vaccines through various no-fault schemes, redact critical information about these products, including their ingredients, and [claims](#) that releasing such documentation will take several

decades, as the FDA did recently regarding its documents related to the Pfizer-BioNTech COVID vaccine.

This is despite the fact that in the 2011 *Bruesewitz v. Wyeth* [decision](#), the U.S. Supreme Court gave considerable latitude to the FDA for, essentially, knowing better than judges and juries, or state lawmakers, how to regulate vaccines.

Despite this legal shielding, plenty of coverage of [adverse reactions](#), and even [deaths](#), following vaccinations is making its way into the media, and to the public consciousness, seemingly negating yet another argument in favor of indemnity.

Furthermore, as many no-fault schemes place the burden on taxpayers and government coffers, these financial costs are ultimately borne by the public.

Arguments that claim shielding vaccine makers from lawsuits also helps to keep the cost of these products down can be called into question on such grounds, especially if the government is the one making deals with vaccine manufacturers and paying for these vaccines.

Costs may be reduced in their purchase price, but the same government and same funds are then used to settle vaccine injury claims.

Such claims from vaccine makers, such as Pfizer for instance, also appear to be disingenuous when considering their [high marketing budgets](#), which in the U.S., far exceed their research and innovation expenditures.

Arguments can be made that such funding could be redirected towards legal claims, towards reducing vaccine and drug prices, or both.

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